Viabahn stent graft compared with prosthetic surgical above-knee bypass in treatment of superficial femoral artery disease

Long-term results of a retrospective analysis

Narges Waezi, MD, Shekhar Saha, MD, Ioannis Bougioukas, MD, Alexander Emmert, MD, Bernhard Christoph Danner, MD, Hassina Baraki, MD, PhD, Ahmad Fawad Jebran, MD, PhD, Dieter Zenker, MD, Tomislav Stojanovic, MD, PhD, Ahmad Fawad Jebran, MD

Abstract
The prosthetic surgical above-knee bypass (pAKB) is a standard therapy in superficial femoral artery (SFA) occlusive disease in absence of suitable vein. Viabahn graft has been established as a promising alternative. Since limited comparative data are available, we conducted a retrospective study to compare long-term outcomes of these 2 therapies in a real-world setting.

Records of 52 patients (60 limbs), who were treated by pAKB (29 limbs) or Viabahn (31 limbs) were reviewed. Patients were followed up by clinical assessment, physical examination, and resting ankle brachial index (ABI) after 3, 6, 12 months and yearly thereafter. Long-term data were available for 97% in the Viabahn and 93% for pAKB after 73±3.7 months (mean±standard error [SE]).

Long-term primary and secondary patencies in Viabahn group were 40% and 70%, respectively, after 63±2.8 months (mean±SE). Total lesion length was 19±11.06 cm (mean±SE), graft size was 6±0.72 mm (mean±SE). Hospital stay was 4.8±0.72 days (mean±SE). Limb salvage was achieved in 90%. Patients in the pAKB group showed a total lesion length of 24.39±1.97 cm (mean±SE), graft size was 7±0.99 mm (mean±SE). Long-term analysis after 83±6.8 months (mean±SE) revealed a primary patency of 78% with a secondary patency of 94%. Hospital stay was 10.4±1.27 days (mean±SE). Limb salvage was ensured in 97%. Long-term primary patency was lower for Viabahn (P=.044), secondary patency (P=.245), and leg salvage (P=.389) were not significantly different. However, hospital stay was shorter (P=.0002) for Viabahn.

Long-term analysis of Viabahn revealed a significantly lower primary patency, a similar secondary patency, limb salvage, and significantly shorter hospital stay when compared with pAKB. Our data suggest that pAKB is still a valuable option in patients suitable for an open operation. However, Viabahn can be used as a less invasive treatment in high risk patients.

Abbreviations: ABI = ankle brachial index, CTA = computed tomography angiography, ePTFE = expanded polytetrafluoroethylene, MRI = magnetic resonance imaging, pAKB = prosthetic surgical above-knee bypass, SE = standard error, SFA = superficial femoral artery, TASC = Transatlantic Intersociety Consensus.

Keywords: ankle brachial index, endovascular, lower extremities, superficial femoral artery disease, surgical above-knee bypass, Viabahn

1. Introduction
The superficial femoral artery (SFA) and the proximal popliteal artery are the most common anatomic sites of stenosis or occlusion among individuals with peripheral arterial disease. Among traditional treatment strategies the surgical above-knee bypass using autologous vein is still considered the “gold standard” in the treatment of SFA occlusive disease. However, technical advances in endovascular therapy have provided us with alternative treatment tools. After encouraging results of the endovascular implantation of a self-expanding expanded polytetrafluoroethylene (ePTFE)/nitinol stent-graft called Hemobahn endoprosthesis (W. L. Gore, Flagstaff, AZ) from an international trial, the graft was modified and introduced as Viabahn endoprosthesis. Although several subsequent studies since that time confirmed the initial respectable patency results, fewer reports exist comparing the outcome of the Viabahn with that of the surgical prosthetic above-knee bypass (pAKB) for the treatment of SFA occlusive disease. We have previously reported on the early and midterm results of our patient cohort. Studies comparing long-term results after pAKB and endovascular therapy with Viabahn are rather scarce. With our current study we aimed to evaluate and compare the long-term outcome of Viabahn endoprosthesis with the surgical above-knee bypass for the treatment of SFA occlusive disease in a real world setting by retrospective analysis of treated patients by both modalities.
2. Materials and methods

2.1. Patients

From 2005 to 2011, 52 consecutive patients (60 limbs) who underwent either surgical pAKB or Viabahn endovascular prosthesis implantation in the superficial femoral artery were identified. Written informed consent for study purposes was obtained from all patients prior to treatment start. The medical records of these patients were retrospectively reviewed, including demographic details, risk factors, clinical characteristics, diagnostic images, type of revascularization procedures, and their results. In all patients, conservative therapy was maxed out. All patients suffered from chronic ischemia and were categorized by Rutherford categories based on symptoms and clinical presentation at the time of the revascularization. Patient demographics and associated risk factors are shown in Table 1.

2.2. Technique

Both techniques were performed under general anesthesia. Viabahn stent-graft implantation was performed using standard small surgical exposure of proximal SFA and subsequent traditional angioplasty stenting techniques. The surgical pAKB was accomplished in the usual surgical fashion. As conduit, ePTFE grafts were chosen. All patients received Heparin (5000 Units) during procedure. After treatment combined antiplatelet therapy with aspirin (100mg/d) and clopidogrel (75mg/d) was administered for at least 6 months and one of them thereafter in the Viabahn group. Patients in the surgical pAKB group received aspirin 100mg/d alone. In case of associated comorbidities requiring oral anticoagulation therapy, warfarin was added to the antiplatelet therapy.

2.3. Follow-up

Follow-up was performed at 1, 3, 6, 12 months and yearly thereafter and included clinical assessment and resting ankle-brachial index (ABI) measurement. In the case of abnormal findings duplex imaging or CT-Angiography (CTA) was performed to confirm the graft patency. Graft patency was analyzed by primary patency and secondary patency. Primary patency was defined as uninterrupted freedom of restenosis or occlusion within the treated vessel and secondary patency was defined as restored graft patency after occlusion or stenosis. Limb salvage was defined as freedom from a major amputation.

2.4. Statistical analysis

In statistical analysis, the two-tailed Fisher exact test was applied to determine differences in patient risk factors and the type of re-intervention. The two-tailed t test was used to calculate differences in patient demographics and hospital stay. Generalized Fisher exact test was used to assess differences in grades of limb ischemia, type of lesion according to TASC II (Transatlantic Intersociety Consensus) classification, and number of run-off arteries. The Kaplan–Meier method with the log-rank test was applied to calculate and compare the rates of graft patency, major amputation, and all cause death in each group. A P value <.05 was considered statistically significant.

3. Results

The retrospective analysis included medical records of 52 patients treated between 2005 and 2011 with either implantation of Viabahn endovascular prosthesis (27 patients, 31 limbs) or femoral to above-knee bypass (25 patients, 29 limbs). No significant difference in demographics and risk factors was found between the 2 treatment groups. Rutherford classification of limb ischemia was used to assess clinical status of patient’s limb prior to treatment (Table 2). There were more limbs with higher ischemia grades (grade 4–5) in the Viabahn group. Statistical analysis revealed this difference in Rutherford class distribution to be significant (P=.032). Number of lower leg vessels (run-off arteries) was explored on preoperative CT- or magnetic resonance imaging (MRI) scans to assess blood outflow in treated limbs (Table 3). Comparison of run-off arteries in both groups showed a significant difference with a better outflow in the pAKB group. Lesion morphology assessment and typing was performed using TASC II classification recommendations as shown in Table 4. The majority of limbs in the Viabahn group presented with TASC II A and B lesions whereas in the pAKB group most of the lesions represented TASC II C and D. This

### Table 1

| Patient demographics and risk factors. | Viabahn group (N=27) | pAKB group (N=25) | P value |
|--------------------------------------|----------------------|-------------------|---------|
| Mean age, (range)                    | 68±7.7 (48–82)       | 65±2.2 (51–78)    | .349    |
| Sex (male)                           | 19                   | 23                | .077\*  |
| Diabetes                             | 6                    | 11                | .140\*  |
| Hyperlipidemia                       | 19                   | 23                | .078\*  |
| CAD                                  | 17                   | 15                | 1\*     |
| Smoking                              | 7                    | 6                 | 1\*     |
| Hypertension                         | 26                   | 24                | 1\*     |
| Renal insufficiency                  | 3                    | 8                 | .093\*  |
| COPD                                 | 4                    | 5                 | .722\*  |

CAD=coronary artery disease, COPD=chronic obstructive pulmonary disease, pAKB=prosthetic above-knee bypass.
\*Two-sided Fisher exact test.
\* Two-sided Fisher exact test.

### Table 2

Rutherford clinical grades of chronic limb ischemia in study patients.

| Rutherford clinical grade | Limbs with Viabahn (N=31) | Limbs with pAKB (N=29) | P value |
|---------------------------|---------------------------|------------------------|---------|
| 0                         | 0                         | 0                      | .032\*  |
| 1                         | 0                         | 0                      |         |
| 2–3                       | 21                        | 27                     |         |
| 4                         | 6                         | 0                      |         |
| 5                         | 4                         | 2                      |         |
| 6                         | 0                         | 0                      |         |

pAKB=prosthetic above-knee bypass.
\*Generalized Fisher exact test.

### Table 3

| Number of run-off arteries by treatment groups. | Number of run-off arteries | Limbs with Viabahn (N=31) | Limbs with pAKB (N=29) | P value |
|-----------------------------------------------|---------------------------|---------------------------|------------------------|---------|
| 1                                             | 6                         | 0                         |                        | .007\*  |
| 2                                             | 13                        | 8                         |                        |         |
| 3                                             | 12                        | 21                        |                        |         |
| Total                                         | 31                        | 29                        |                        |         |

pAKB=prosthetic above-knee bypass.
\* Generalized Fisher exact test.
difference was statistically significant \((P < .0001)\). This distribution of lesion types conforms to the recommendations of the TASC II concerning treatment of femoropopliteal lesions.\(^{15}\)

Technical success was achieved in all treated patients. In all, 50 Viabahn endoprosthesis were implanted in 31 limbs, with a mean of \(2 \pm 0.83\ SE\) grafts per limb. The mean treated lesion length was \(19 \pm 11.06\ cm\ SE\). The mean Viabahn diameter was \(6\ mm\) (range, 5–8). In the surgical pAKB group, ePTFE grafts were used in all patients. Patients showed a mean total lesion length of \(24.39 \pm 1.97\ SE\ cm\). Procedural related or early postoperative complications were not noted in both groups. Analysis of hospital stay was performed for both groups and revealed a significantly shorter duration of hospital stay \((P = .0002)\) in the Viabahn group with a mean of \(4.8 \pm 0.75\ SE\ days\) whereas the mean hospital stay in the surgical group was found to be \(9.8 \pm 1.05\ SE\ days\) (Table 5).

### 3.1. Long-term follow-up

Long-term follow-up data were available for 30 limbs (97%) in the Viabahn group and 27 limbs (93%) in the pAKB group after \(73 \pm 3.7\ SE\ months\) (mean \(\pm SE\)). In the Viabahn group the mean long-term follow-up time was \(63 \pm 2.78\ SE\ months\) (Table 5). One patient (1 limb) was lost to follow-up. Five patients died during follow-up. All deaths were not related to SFA disease. Stent-graft failure was observed in 19 limbs (61%) due to thrombosis. There was no Viabahn graft thrombosis during post-procedural hospital stay. Two stent-graft failures occurred during the first month after implantation, 8 stent-grafts failed by the end of the first year after implantation. The remaining 9 stent-graft occlusions happened after a mean period of \(34 \pm 6.2\ months\). Among the 19 limbs with failed Viabahn grafts 2 limbs were in Rutherford clinical grade 5 and 4 limbs in Rutherford clinical grade 4, the remaining 13 limbs in Rutherford clinical grade 2 to 3 previous to therapy. The majority of the limbs with graft failure had 3 \((9 limbs)\) or 2 \((8 limbs)\) run-off arteries. One run-off artery was evident in only 2 limbs with occluded grafts. The occluded limbs presented with lesions of TASC II type A \((6 limbs)\), B \((7 limbs)\), C \((6 limbs)\) but not type D prior to treatment. Two patients with occluded grafts had interrupted the antiplatelet therapy because of other surgical procedures. Failed Viabahn grafts were treated with thrombectomy alone in 3 limbs. Additional transluminal angioplasty \((3 limbs)\) or additional implantation of new Viabahn grafts \((9 limbs)\) was required due to progression of the disease or restenosis at the distal edge of the stent-graft. In 1 patient \((1 limb)\) surgical femoro-popliteal bypass to the distal segment of the popliteal artery had to be done. Three limbs were managed conservatively.

In the pAKB group the mean long-term follow-up time was \(83 \pm 6.79\ months\) (Table 5). One patient \((2 limbs)\) was lost to follow-up. Seven patients expired during follow-up due to reasons not related to SFA disease. In the pAKB group bypass failure due to thrombosis were noted in 11 limbs \((38\%)\). None of the graft thrombosis occurred during post-procedural hospital stay. Five bypass grafts failed during the first year after the operation, 1 within the first month, the remaining 4 by the end of the first year after bypass implantation. The remaining 6 bypass graft occlusions took place after a mean period of \(47 \pm 7.6\ months\). Among the patients with failed bypasses only 1 patient had suffered from Rutherford clinical grade 5, the remaining patients had shown Rutherford clinical grade 2 to 3 previous to therapy. With respect to the number of run-off arteries, 4 of the affected limbs presented with 2 run-off arteries, 7 limbs in contrast with 3 run-off arteries. Limbs with 1 run-off artery were not affected by graft occlusion. Concerning the TASC II type of lesions, occluded limbs were presented with type A \((2 limbs)\), B \((1 limb)\), D \((8 limbs)\) but not type C. Ten of the occluded grafts underwent successfully redo interventions. One patient \((1 limb)\) was treated conservatively. Redo procedures included solely thrombectomy \((6 limbs)\), additional implantation of Viabahn at the level of the distal anastomosis \((3 limbs)\), and surgical femoro-popliteal bypass to the distal segment of the popliteal artery \((1 limb)\).

Major amputation was needed in 3 patients in the Viabahn group \((10\%)\) and in 1 patient in the pAKB group \((4\%)\) after recurrent graft failure. The difference was not statistically significant (Table 5).

Primary patency rates calculated by the Kaplan–Meier method were 40% in the Viabahn group and 78% in the pAKB group (Table 5, Fig. 1). This difference proved to be statistically significant \((P = .044)\). Secondary patency rates in the Viabahn group did not differ significantly from the pAKB group as shown in Fig. 2 \((70\% vs 94\%, P = .243; Table 5)\). Subgroup analysis was performed to evaluate the influence of various factors such as number of run-off vessels, grade of limb ischemia, TASC II lesion type, and stent size on primary and secondary patency rates in each treatment group and comparing both treatment groups (Tables 6 and 7; Figs. 3–6). This analysis revealed that patients

![Table 4](https://example.com/table4.png)

| TASC II grades | Limbs with Viabahn (N = 31) | Limbs with pAKB (N = 29) | \(P\) |
|----------------|----------------------------|--------------------------|------|
| A | 10 | 3 | .001* |
| B | 11 | 1 | |
| C | 9 | 2 | |
| D | 12 | 23 | |

\(\text{pAKB} = \text{prosthetic above-knee bypass, TASC = Transatlantic Intersociety Consensus.}\)

*Generalized Fisher exact test.

![Table 5](https://example.com/table5.png)

| Follow-up data according to treatment groups. | Viabahn group (limbs, N = 31) | pAKB group (limbs, N = 29) | \(P\) value |
|-----------------------------------------------|-------------------------------|--------------------------|-------------|
| Follow-up (mo, mean) | \(63 \pm 2.78\ SE\) | \(83 \pm 6.79\ SE\) | .001* |
| Limbs lost to FU \(n\) | 1 (3.2) | 2 (6.9) | .606 |
| Deaths \(n\) | 5 (16.1) | 7 (24.1) | .816 |
| Amputations \(n\) | 3 (9.7) | 1 (3.5) | .389 |
| Graft failure | 19 (61.3) | 11 (37.9) | .044 |
| Hospital stay (d, mean) | \(4.77 \pm 0.75\ SE\) | \(9.83 \pm 1.05\ SE\) | .002 |
| Type of re-intervention | | | |
| Conservative | 3 (9.7) | 1 (3.4) | .613 |
| Thrombectomy | 3 (9.7) | 6 (20.7) | .292 |
| Thrombectomy + TA | 3 (12.9) | 0 | .238 |
| Thrombectomy + Viabahn | 9 (25.8) | 3 (10.3) | .107 |
| Femoro-popliteal-bypass | 1 (3.2) | 1 (3.4) | 1 |
| Cumulative patencies | | | |
| Primary, \% | 40 | 78 | .044 |
| SE | 5.74 | 9.08 | |
| Secondary, \% | 70 | 94 | .245 |
| SE | 4.81 | 7.68 | |

\(\text{Numbers in parentheses are percentages. FU} = \text{follow up, pAKB} = \text{prosthetic above-knee bypass, SE} = \text{standard error, TA} = \text{transluminal angioplasty.}\)

*Log rank test.

**Two-sided Fisher exact test.**

---

Waezi et al. Medicine (2018) 97:40 www.md-journal.com
with 2 or 3 run-off vessels who received a pAKB showed a significantly higher primary patency compared with the same cohort of patients in the Viabahn group (78% vs 36%; \( P = .009 \); Fig. 3). The secondary patency rates were similar in both groups and cohort of patients. No significant differences concerning patency rates were detected dividing the patient cohort into groups according the grade of limb ischemia, TASC II lesion type, and stent size. However, this subgroup analysis has to be looked at cautiously due to an overall small patient cohort and small number of patients in some subgroups.

### 4. Discussion

Bypass surgery especially with the use of autologous vein as graft material is still considered the gold standard for SFA disease and recommended therefore as first-line treatment if revascularization is required.\(^{[1]}\) Several studies have convincingly demonstrated the superiority of autologous saphenous vein material over prosthetic bypass grafts.\(^{[16–19]}\) The latter are nevertheless used more often in the daily routine due to several legitimate reasons. The lack of suitable venous material and the idea to preserve the vein for below-knee bypasses, where it evidentially provides superior results compared with synthetic grafts,\(^{[20,21]}\) have led to the widespread use of prosthetic bypass material such as Dacron and ePTFE. Among synthetic grafts the use of Dacron or ePTFE has not shown any significant difference in outcome.\(^{[22–24]}\) In recent years an evolution in the field of endovascular intervention has taken place. Starting with percutaneous transluminal angioplasty to treat SFA disease with moderate patency results\(^{[25]}\) subsequent step-up with self-expanding nitinol stents could provide slightly better results.\(^{[26–28]}\) However, late clinical failure caused by in-stent stenosis and stent fracture raised considerable concern.\(^{[29]}\) With the introduction of endovascular prosthesis for peripheral occlusive disease (Hemobahn, later Viabahn, W. L. Gore, Flagstaff, AZ) higher patency rates and reduced delayed stent graft failure could be achieved.\(^{[13–17]}\) Since reports about comparison of Viabahn graft with pAKB were scarce, we previously published a retrospective analysis of our current patient cohort demonstrating significantly lower primary patency rates for patients treated with the Viabahn stent graft after a mean of 24.5 months.\(^{[13]}\) Studies comparing the efficacy of the Viabahn graft with the surgical prosthetic AK bypass for the treatment of SFA occlusive disease on the long run are still very limited. We therefore evaluated long-term data of our patient cohort.

Long-term follow-up data were available for 97% in the Viabahn group and 93% in pAKB group after a mean of 73 ± 3.7 SE months. McQuade et al.\(^{[12]}\) who conducted the only so far published long-term study on comparing Viabahn with pAKB for the treatment of SFA occlusive disease, collected follow-up data of 64% and 52% of the patients in the Viabahn and pAKB group after 48 months, respectively. Primary patency rates in the Viabahn group of our patients cohort with a mean lesion length of 15.03 cm were significantly lower compared with the pAKB group (40% vs 78%, \( P = .044 \)), whereas secondary patency rates
Figure 2. Long-term secondary patency during follow-up by Kaplan–Meier analysis (log rank test: \( P = .245 \)).

Table 6

| Subgroup analysis of primary and secondary patency rates compared between treatment groups. |
|------------------|------------------|------------------|------------------|
|                  | Viabahn group    | pAKB group       | \( P \)-value    |
|                  | \( n \)  | %     | SE  | \( n \)  | %     | SE  |      |
| Primary patency by run-off |      |      |     |      |      |     |      |
| 2–3 run-off      | 25   | 36.05 | 5.87 | 29   | 78.22 | 9.08 | .009 |
| 1 run-off        | 6    | 45.11 | 10.44| 0    | 0.00  | 0.00 |    |
| Secondary patency by run-off |      |      |     |      |      |     |      |
| 2–3 run-off      | 25   | 72.30 | 4.87 | 29   | 93.95 | 7.68 | .319 |
| 1 run-off        | 6    | 45.07 | 10.16| 0    | 0.00  | 0.00 |    |
| Primary patency by TASC II |      |      |     |      |      |     |      |
| A                | 10   | 44.24 | 9.83 | 3    | 43.33 | 21.14| .968 |
| B                | 11   | 33.41 | 7.67 | 1    | 47.00 | 0.00 | .842 |
| C                | 9    | 31.67 | 9.03 | 2    | 97.00 | 0.00 | .159 |
| D                | 1    | 64.00 | 0.00 | 23   | 80.07 | 10.41| .517 |
| A–B              | 21   | 40.11 | 6.76 | 4    | 44.25 | 15.87| .606 |
| C–D              | 10   | 35.30 | 8.83 | 25   | 83.35 | 9.70 | .103 |
| Secondary patency by TASC II |      |      |     |      |      |     |      |
| A                | 10   | 74.38 | 4.37 | 3    | 62.00 | 23.68| .613 |
| B                | 11   | 72.14 | 7.71 | 1    | 84.00 | 0.00 | .973 |
| C                | 9    | 53.11 | 9.26 | 2    | 97.00 | 0.00 | .292 |
| D                | 1    | 64.00 | 0.00 | 23   | 95.53 | 8.55 | .643 |
| A–B              | 21   | 74.66 | 4.72 | 4    | 66.63 | 18.17| .720 |
| C–D              | 10   | 55.50 | 8.63 | 25   | 97.38 | 7.88 | .214 |

pAKB = prosthetic above-knee bypass, SE = standard error, TASC = Transatlantic Intersociety Consensus.  
\*All patency rates were calculated by using log rank testing.
Table 7
Subgroup analysis of primary and secondary patency rates in each treatment group.

| Run-off arteries | 3 run-off |  | 2 run-off |  | 1 run-off |  | P-value |
|------------------|-----------|---|-----------|---|-----------|---|---------|
|                  | n | % | SE | n | % | SE | n | % | SE |        |
| Viabahn group    |   |   |    |   |   |    |   |   |    |        |
| Primary patency  | 12| 32.25| 7.84| 13| 39.00| 8.60| 6 | 45.11| 10.44| .546   |
| Secondary patency| 12| 77.71| 4.80| 13| 66.04| 7.62| 6 | 45.07| 10.16| .458   |
| pAKB group       |   |   |    |   |   |    |   |   |    |        |
| Primary patency  | 21| 84.00| 9.84| 8 | 62.00| 17.51| 0 | .491  |
| Secondary patency| 21| 95.41| 8.36| 8 | 86.25| 15.17| 0 | .838  |

TASC II

| A-B          | C-D          |        |
|--------------|--------------|---------|
| n | % | SE | n | % | SE |        |
| Viabahn group|   |   |    |   |   |        |
| Primary patency| 21| 40.11| 6.76| 10| 35.30| 8.83| .904   |
| Secondary patency| 21| 74.66| 4.72| 10| 55.50| 8.63| .425   |
| pAKB group    |   |   |    |   |   |        |
| Primary patency| 4 | 44.25| 15.87| 25| 83.35| 9.70| .137   |
| Secondary patency| 4 | 66.63| 18.17| 25| 97.38| 7.88| .144   |

Stent size 5 mm 6 mm 7 mm

| n | % | SE | n | % | SE | n | % | SE |        |
|---|---|----|---|---|----|---|---|----|---------|
| Viabahn group|   |   |    |   |   |    |   |   |        |
| Primary patency| 7 | 32.43| 9.54| 18| 42.03| 7.36| 6 | 33.17| 10.54| .977   |
| Secondary patency| 7 | 53.79| 7.46| 18| 72.19| 5.73| 6 | 72   | 10.95| .488   |

pAKB = prosthetic above-knee bypass, SE = standard error, TASC = Transatlantic Intersociety Consensus.

*All patency rates were compared by using log rank testing.

Figure 3. Long-term primary patency during follow-up by Kaplan–Meier analysis according to preoperative number of run-off arteries. Patients with 2 or 3 run-off arteries in each treatment group are compared (log rank test: P = .009).
Figure 4. Long-term secondary patency during follow-up by Kaplan–Meier analysis according to preoperative number of run-off arteries. Patients with 2 or 3 run-off arteries in each treatment group are compared (log rank test: \( P = .319 \)).

Figure 5. Long-term primary patency during follow-up by Viabahn stent-graft size versus pAK bypass using Kaplan–Meier analysis (log rank test: \( P = .132 \)).
did not differ significantly (70% vs 94%, \( P = .245 \)). McQuade et al.\(^{12}\) reported in contrast to our results a slightly higher primary patency rate of 48% for Viabahn in patients with a mean lesion length of 25.6 cm and a markedly lower primary patency rate of 58% for pAKB after 48 months. Fischer et al.\(^6\) demonstrated long-term primary patency rates of 45% 5 years after implantation of Viabahn grafts in SFA lesions with a mean length of 10.7 cm. Geraghty et al.\(^30\) describe in the results of the VIBRANT trial remarkable low primary patency rates of 24.2% 3 years after Viabahn graft implantation in SFA lesions with a mean length of 19 cm. The primary patency rate in the Viabahn group of our study population after a mean of 73 ± 3.7 SE months is comparable with above mentioned studies. In contrast to the limited data on comparing Viabahn with pAKB we conclude a significantly lower primary patency rate for the endovascular graft approach. This could be explained plausibly by a significantly higher Rutherford clinical grade of limb ischemia in our study patients who received a Viabahn graft. Lower leg vessel supply is distributed significantly unequal in our patient cohort. All patients with pAKB had 2 or 3 run-off vessels, whereas the majority of patients in the Viabahn group presented with 1 or 2 run-off vessel supply. But comparing only patients with 2 or 3 run-off arteries in each treatment arm revealed still a significantly lower long-term primary patency for Viabahn graft.

The rate of limb loss on the long run was not statistically different in both treatment groups in our study. Size of implanted Viabahn grafts had no impact on the long-term outcome considering patency rates. Both observations are consistent with the analysis of McQuade et al.\(^{12}\). The hospital stay in the Viabahn group was significantly shorter compared with the pAKB as reported in other investigations.\(^{11,12}\)

Our study has several recognized limitations including the retrospective character, lack of randomization, small total patient number, and a single center experience. However, we could collect long-term data from a high percentage of the treated patients in both groups. This data allow us to report on the efficacy of both the conventional and endovascular approach for the treatment of SFA occlusive disease in real world setting beyond the so far reported time of investigation.

5. Conclusion

Our long-term analysis of treatment with Viabahn graft in a real-world setting revealed a significantly lower primary patency rate, when compared with pAKB after 73 ± 3.7 months (mean ± SE) while showing a similar secondary patency rate. Limb salvage is comparable in both treatment groups even after a mean of 73 ± 3.7 months. However, patients treated with Viabahn graft showed a significantly shorter hospital stay. Our data suggest that pAKB is still a valuable option in patients suitable for an open operation. However, the endovascular Viabahn prosthesis can be used as a less invasive approach to treat SFA occlusive disease in
high risk surgical candidates and offers a cost-effective therapy due to a reduced hospital stay. Therefore great attention has to be paid to patient selection in the daily clinical routine as graft patency is strongly dependent on patient’s cardiovascular risk factors. Our data also suggest that patients with Viabahn grafts should be followed up closely in order to recognize graft failure early and intervene adequately because the secondary patency is acceptable. Further studies are warranted to especially evaluate the role of Viabahn endoprosthesis in patients with complex lesions in comparison to pAKB.

Acknowledgments
The authors acknowledge support by the German Research Foundation and the Open Access Publication Funds of the Goettingen University.

Author contributions
Conceptualization: Tomislav Stojanovic, Ahmad Fawad Jebran
Data curation: Narges Waezi, Shekhar Saha
Formal analysis: Narges Waezi, Ahmad Fawad Jebran
Funding acquisition: Alexander Emmert, Bernhard Christoph Danner
Investigation: Narges Waezi, Shekhar Saha, Ahmad Fawad Jebran.
Methodology: Narges Waezi, Shekhar Saha, Ahmad Fawad Jebran
Project administration: Dieter Zenker, Alexander Emmert
Resources: Hassina Baraki, Ingo Kutschka
Software: Ioannis Bougioukas, Alexander Emmert
Supervision: Tomislav Stojanovic, Ahmad Fawad Jebran
Validation: Tomislav Stojanovic, Ahmad Fawad Jebran
Visualization: Narges Waezi, Shekhar Saha, Ahmad Fawad Jebran
Writing – original draft: Narges Waezi, Shekhar Saha, Ahmad Fawad Jebran
Writing – review & editing: Narges Waezi, Shekhar Saha, Ahmad Fawad Jebran

References
[1] Gerhard-Herman MD, Gornik HL, Barrett C, et al. 2016 AHA/ACC guideline on the management of patients with lower extremity peripheral artery disease: executive summary: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Circulation 2017;135:e686–725.
[2] Gable D. Role of total endoluminal superficial femoral artery bypass. J Cardiovasc Surg (Torino) 2011;52:683–700.
[3] Lammer J, Dake MD, Bleyen J, et al. Peripheral arterial obstruction: prospective study of treatment with a transannually placed self-expanding stent-graft. International Trial Study Group, Radiology 2000;217:95–104.
[4] McQuade K, Gable D, Hohman S, et al. Randomized comparison of ePTFE/nitinol self-expanding stent graft vs prosthetic femoral-popliteal bypass in the treatment of superficial femoral artery occlusive disease. J Vasc Surg 2009;49:109–15. 116.e1–9; discussion 116.
[5] Jahnke T, Andrensen R, Müller-Hulsbeck S, et al. Hemobahn stent-grafts for treatment of femoral-popliteal arterial obstructions: midterm results of a prospective trial. J Vasc Interv Radiol 2003;14:41–51.
[6] Fischer M, Schwabe C, Schulte KL. Value of the hemobahn/viabahn endoprosthesis in the treatment of long chronic lesions of the superficial femoral artery: 6 years of experience. J Endovasc Ther 2006;13:281–90.
[7] Hartung O, Otero A, Dubuc M, et al. Efficacy of Hemobahn in the treatment of superficial femoral artery lesions in patients with acute or critical ischemia: a comparative study with claudicants. Eur J Vasc Endovasc 2005;30:300–6.
[8] Alimi YS, Hakam Z, Hartung O, et al. Efficacy of Viabahn in the treatment of severe superficial femoral artery lesions: which factors influence long-term patency? Eur J Vasc Endovasc Surg 2008;35:346–52.
[9] Faraj N, Srivastava A, Pershad A. One-year outcomes for recanalization of long superficial femoral artery chronic total occlusions with the Viabahn stent graft. J Invasive Cardiol 2009;21:278–81.
[10] Obki T, Kuchikawa K, Yokoi H, et al. Outcomes of the Japanese multicenter Viabahn trial of endovascular stent grafting for superficial femoral artery lesions. J Vasc Surg 2017;66:130.e1–42.e1.
[11] Kedora J, Rohmann S, Garrett W, et al. Randomized comparison of percutaneous Viabahn stent grafts vs prosthetic femoral-popliteal bypass in the treatment of superficial femoral arterial occlusive disease. J Vasc Surg 2007;45:10–6. discussion 16.
[12] McQuade K, Gable D, Pearl G, et al. Four-year randomized prospective comparison of percutaneous ePTFEnitinol self-expanding stent graft versus prosthetic femoral-popliteal bypass in the treatment of superficial femoral artery occlusive disease. J Vasc Surg 2010;52:584–90. discussion 590–591, 591.e1–591.e7.
[13] Jebran AF, Popov AF, Zenker D, et al. Is there an alternative to the surgical above-knee bypass in treatment of superficial femoral artery disease? Experiences with Viabahn stent graft. Vasc Endovascular Surg 2013;47:502–6.
[14] Rutherford RB, Baker JD, Ernst C, et al. Recommended standards for reporting dealing with lower extremity ischemia: revised version. J Vasc Surg 1997;26:517–38.
[15] Norgren L, Hiatt WR, Dormandy JA, et al. Inter-Society consensus for the management of peripheral arterial disease (TASC II). J Vasc Surg 2007;45:67–78.
[16] Donker JMW, Ho GH, Te Slaa A, et al. Midterm results of autologous saphenous vein and ePTFE pre-cuffed bypass surgery in peripheral arterial occlusive disease. Vasc Endovascular Surg 2011;45:598–603.
[17] Klinkert P, Scheipers A, Burger DHC, et al. Vein versus polytetrafluoroethylene in above-knee femoropopliteal bypass grafting: five-year results of a randomized controlled trial. J Vasc Surg 2003;37:149–55.
[18] Klinkert P, Post PN, Breslau PJ, et al. Saphenous vein versus PTFE for above-knee femoropopliteal bypass. A review of the literature. Eur J Vasc Endovasc Surg 2004;27:357–62.
[19] Ambler GK, Twine CP. Graft type for femoropopliteal bypass surgery. Cochrane Database Syst Rev 2018;2:CD001487.
[20] Dorigo W, Pulii R, Pifaretti G, et al. Results from an Italian multicentric registry comparing heparin-bonded ePTFE graft and autologous saphenous vein in below-knee femoro-popliteal bypass surgeries. J Cardiovasc Surg (Torino) 2012;53:187–94.
[21] Tilanus HW, Oberhop T, Van Uerk H. Saphenous vein or PTFE for femoropopliteal bypass. A prospective randomized trial. Ann Surg 1985;202:780–2.
[22] Takagi H, Goto SN, Matsui M, et al. A contemporary meta-analysis of Dacron versus polytetrafluoroethylene grafts for femoropopliteal bypass grafting. J Vasc Surg 2010;52:232–6.
[23] Abbott WM, Green RM, Matsumoto T, et al. Prosthetic above-knee femoropopliteal bypass grafting: results of a multicenter randomized prospective trial. Above-Knee Femoropopliteal Study Group. J Vasc Surg 1997;25:19–28.
[24] Rychlik IJ, Davey P, Murphy J, et al. A meta-analysis to compare Dacron versus polytetrafluoroethylene grafts for above-knee femoropopliteal bypass artery. J Vasc Surg 2014;60:506–15.
[25] Met R, Van Lienden KP, Koelemay MJW, et al. Subintimal angioplasty of a combined femoral artery occlusive disease. J Endovasc Ther 2005;12:676–87.
[26] Schilling M, Sabeti S, Loewe C, et al. Balloon angioplasty versus implantation of nitinol stents in the superficial femoral artery. N Engl J Med 2006;354:1879–88.
[27] Linard JR, Katzen BT, Schenett D, et al. Nitinol stent implantation vs. balloon angioplasty for lesions in the superficial femoral and proximal popliteal arteries of patients with claudication: three-year follow-up from the RESILIENT randomized trial. J Endovasc Ther 2012;19:1–9.
[28] Dick P, Wallner H, Saben S, et al. Balloon angioplasty versus stenting with nitinol stents in intermediate length superficial femoral artery lesions. Catheter Cardiovasc Intervent Radiol 2008;31:687–97.
[29] Geraghty PJ, Mewissen MW, Jaff MR, et al. VIBRANT investigators. Three-year results of the VIBRANT trial of VIABAHN endoprosthesis versus bare nitinol stent implantation for complex superficial femoral arterial occlusive disease. J Vasc Surg 2013;58:386.e4–95.e4.