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Performance of the BioIntegral Bovine Pericardial Graft in Vascular Infections: VASCular No-REact Graft Against INfection Study

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Background: Vascular graft and endograft infections (VGEI) and native vessel infections (NVI) remain considerable challenges in vascular surgery, leading to high mortality and morbidity rates. Although in situ reconstruction is the preferred treatment, the material of choice is still a source of debate. Autologous veins are considered the first choice; however, xenografts may be an acceptable alternative. The performance of a biomodified bovine pericardial graft is assessed when implemented in an infected vascular area.

Methods: This is a prospective multicenter cohort study. Patients who underwent reconstruction for VGEI or NVI with a biomodified bovine pericardial bifurcated or straight tube graft were included from December 2017 until June 2021. The primary outcome measure was reinfection at mid-term follow-up. Secondary outcome measures included mortality, patency, and amputation rate.

Results: Thirty-four patients with vascular infections were included, of which 23 (68%) had an infected Dacron prosthesis after primary open repair and 8 (24%) had an infected endovascular graft. The remaining 3 (9%) had infected native vessels. At secondary repair, 3 (7%) patients had an in situ aortic tube reconstruction, 29 (66%) had an aortic bifurcated reconstruction, and 2 (5%) had an iliac-femoral reconstruction. At 1-year follow-up after the BioIntegral bovine pericardial graft reconstruction, the reinfection rate was 9%. The 1-year infection-related and procedure-related mortality rate was 16%. The occlusion rate was 6% and in total 3 patients underwent a lower limb amputation during the 1-year follow-up period.

Conclusions: In situ reconstruction as treatment of (endo)graft and native vessel infections remains a challenge and reinfection looms as a potential consequence. In cases where time is of essence or when autologous venous repair is not feasible, a swift available solution is needed. The BioIntegral biomodified bovine pericardial graft may be an option as it shows reasonable results in terms of reinfection, in aortic tube and bifurcated grafts.

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INTRODUCTION

Vascular infections include infections of native vessels as well as infections of prosthetic grafts (including endografts) and are associated with high rates of mortality and morbidity. Infectious aortic aneurysms are rare, with a reported incidence of approximately 4.5%.[1,2] The reported incidence of vascular graft and endograft infections (VGEI) is even lower, ranging between 0.6 and 5.0% at the level of the aortoiliac tract.[3]

To date, the best curative option is surgical intervention. Until a decade ago, removal of the infected graft followed by extra-anatomic prosthetic bypass revascularization was a frequently used procedure. However, this may involve significant complications, such as aortic stump blowout, poor long-term patency, and reinfection (especially at the groin).[4] Today, extra-anatomic reconstruction has largely been replaced by in situ reconstruction (ISR).[5] ISR includes surgical removal of the infected material and debridement of the surrounding tissue, followed by vascular reconstruction at the level of the previously infected area. This procedure is usually combined with antibiotic therapy to achieve definitive eradication.[6]

Unfortunately, there is a lack of consensus on the most appropriate material for vascular reconstruction, including autologous veins, cryopreserved allografts, rifampicin-bonded or silver-coated synthetic grafts, and xenografts.[7–11] The use of infection-resistant material is desirable and autologous vein is the best option for this purpose, with the great saphenous or deep femoral vein being most commonly used.[12] However, these veins may be either unavailable or of insufficient size and length, as past research showed that during harvesting, only 63–75% of the veins appeared suitable for ISR.[13,14] Moreover, vein harvesting extends operating time and thereby increases the risk of site infection, with a reported prevalence of 2–12%.[15–17] Quickly available infection-resistant grafts are essential if autologous veins are not available, if the patient is unable to endure prolonged surgery, or in an emergency setting.

The use of synthetic grafts or allografts has disadvantages, such as reinfection and availability. Modified xenografts are a relatively new treatment strategy for reconstruction in infected areas. Examples include xenogenous tissues such as bovine pericardium and vascular grafts containing bovine collagen.[18–20] A biological replacement of porcine or bovine matrix could be a reasonable alternative.[21] Biologic xenopericardial conduit has demonstrated anti-infective properties to lower the risk of (re)infection with proven long-term durability in cardiothoracic cases; for example, in aortic root replacement.[22,23] Self-made bovine pericardial grafts have shown promising results as for eradication of the infection and no signs of graft degeneration after a median of 15 months, however, the graft is not ready to use on the shelf, which might be necessary in acute cases.[24] Therefore, a bifurcated biologic xenopericardial instant usable graft is preferable.

The aim of the study was to evaluate the performance of the BioIntegral biomodified bovine pericardial tube and bifurcated grafts (BioIntegral Surgical's nonvalved conduit) in patients with a native vascular infection or vascular (endo)graft infection.

METHODS

Design of the Study

A multicenter prospective cohort study was performed in 6 tertiary referral hospitals in the Netherlands. Patients with an acute aortoiliac symptomatic native vascular infection (NVI) or VGEI who needed a reconstruction, without suitable autologous veins, were enrolled in a prospective clinical registry between December 2017 and June 2021. Patients eligible for autologous vein reconstruction, peripheral bypasses, and arteriovenous fistula access were excluded from this study. Diagnosis of NVI/VGEI was based on a combination of clinical, laboratory, and radiological signs, intraoperative findings, and microbiological/histopathological tissue analyses. Diagnostic imaging was conducted by computed tomography (CT) scanning and/or FDG-PET/CT (^{18}F-fluoro-D-deoxyglucose positron emission tomography/CT) scanning.

The study design and follow-up protocol were approved by the institutional review board (METC registration number: R16.085). All patients gave informed consent to use the proprietary bovine pericardial tube or bifurcated graft and authorized the use of their patient data. Data were electronically stored in agreement with the Declaration of Helsinki—Ethical Principles for Medical Research Involving Human Subjects.[25] Furthermore, data were processed and analyzed anonymously.

Data Collection

Data including patient demographics, comorbidities, clinical presentation, type of infection (native/graft), surgery urgency, localization, type

of bovine pericardial conduit, antimicrobial treatment, postoperative complications, and mortality were collected. Comorbidities were classified according to the reporting standards of the Society for Vascular Surgery.[26]

Outcome Measures and Follow-up Schedule

The primary outcome measure was reinfection and secondary outcome measures were mortality (early and late), infection-related mortality, occlusion, and amputation.

Follow-up outpatient visits at 3 and 12 months postprocedure included physical examination, wound inspection, computed tomography angiography (CTA), and when indicated, additional laboratory tests, and/or additional radiological/nuclear examinations.

Device Characteristics

The bovine pericardial graft, named the No-React® nonvalved conduit (Biointegral Surgical Inc., Mississauga, ON, Canada), is a stentless xenograft. The surface treatment (sealing the top layer via a proprietary heparin-rinsing technique) aims to provide biocompatibility, promoting endothelialization and therefore natural anti-infective defenses.

The graft is available in different-sized aortic tube grafts, from 19 × 19 mm to 25 × 25 mm, and bifurcated grafts from 16 × 8mm to 20 × 10 mm, to be used in aortic-bi-iliac, and aortic-bi-femoral reconstructions.

Surgical Procedure

The procedure involved the removal of infected tissue and/or graft material, extensive local debridement, and rinsing with saline. The most suitable bovine pericardial graft, matching with the native vessel diameters 1:1, was chosen by the surgeon. The procedure was performed electively or in an emergency setting. Postoperative antimicrobial treatment was administered intravenously for 2 weeks and orally continued until 6 weeks. Anticoagulation therapy was recommended by the study protocol, consisting of antiplatelet therapy.

Statistics

Categorical data are presented as numbers, with percentages in brackets. Continuous variables are presented as mean values with standard deviations, or as median values with quartiles for skewed distributed data sets. Whether data were normally distributed was assessed by means of normality plots. Data analyses were performed using SPSS version 25.0 (IBM, Chicago, IL, USA) and mostly descriptive statistics were performed.

RESULTS

Patient Characteristics

A total of 34 consecutive patients were included (94% male). The median age was 70.5 years (61.8—73.3) and functional status was impaired in 35% of the patients. The most common comorbidities were hypertension (71%), hyperlipidemia (53%), impaired cardiac function (41%), and renal insufficiency (29%). Patients had a mean of 1.0 (1.0—2.0) previous vascular interventions and 44% of the patients reported using or recently having used tobacco (Table I).

Eleven patients had fever and 5 had tachycardia preoperatively. Nearly all (88%) showed clinical signs of infection, including active bleeding aortic duodenal fistula and a septic blowout of a groin anastomosis, based on dehiscence of the suture line due to infection. The 4 patients who were clinically asymptomatic had an occlusion of the primary graft or were referred based on elevated serum infection markers. More than half (22; 65%) showed a purulent infection site. C-reactive protein was elevated in 79% of the patients with a median of 31.0 (11.5—103.5) and leukocytes were elevated in 61% with a mean of 12.0 (4.9). There were 7 (21%) patients who met the criteria for sepsis. Two (6%) of the primary grafts were occluded at presentation (Table II).

Cultures were taken in 100% of the patients, of which 25 (74%) were positive. In 48% of the positive cultures, multiple bacteria were involved.

Intraoperative Results

With regard to the type of explant, most patients had a regular Dacron prosthesis (68%) or an endovascular graft (24%) in situ. Figure 1 shows an intraoperative view of an explanted endovascular aneurysm repair, infected with *Listeria* species. One had a polytetraflouroethylene prosthesis, and one patient had an infected pericardial patch in the groin. In addition, 3 had a mycotic aneurysm as an indication for using the BioIntegral bovine pericardial graft (Table III).

Perioperative antibiotics were used in 91% of the patients. All patients received postoperative antimicrobial treatment, however, some varied in order of duration and route of administration. Intravenous antibiotic treatment was given for 2 weeks in 97%

Table I. Baseline patient characteristics

	Research group ($N = 34$)
Age[a]	70.5 (61.8−73.3)
Sex (male)[b]	32 (94%)
BMI (kg/m^2)[a]	25.6 (4.2)
Comorbidities	
Hypertension[b]	
None	10 (29%)
Controlled with 1 drug	16 (47%)
Controlled with 2 drugs	5 (15%)
Requiring >2 drugs or uncontrolled	3 (9%)
Hyperlipidemia[b]	
None	16 (47%)
Elevated without drug treatment	10 (29%)
Elevated with drug and diet treatment	8 (24%)
Diabetes mellitus[b]	
None	27 (79%)
Controlled by oral medication	2 (6%)
Controlled by insulin	5 (15%)
Cardiac status[b]	
No limitation of physical activity	20 (59%)
Slight limitation of physical activity	13 (38%)
Marked limitation of physical activity	1 (3%)
Pulmonary status[b]	
No dyspnea	31 (91%)
Physical activity results in dyspnea	2 (6%)
Limitations in physical activity due to dyspnea	1 (3%)
Renal status[b]	
Normal	24 (71%)
GFR 30−59 mL/min/1.73 m^2	8 (24%)
GFR 15−29 mL/min/1.73 m^2	2 (6%)
Functional status[b]	
No impairment	22 (65%)
Impaired but able to carry out ADL without assistance	11 (32%)
Requiring total assistance for ADL/nonambulatory	1 (3%)
Tobacco use[b]	
None or remote (>10 years ago)	11 (32%)
Quit 1−10 years ago	8 (24%)
Current within the last year, smoking <1 pack per day	11 (32%)
Current within the last year, smoking >1 pack per day	4 (12%)
Previous interventions[a]	1.0 (1.0−2.0)

Data are presented as [a]mean/median with the SD/P_{25}-P_{75} between brackets or as [b]N with the percentages between brackets.
BMI, body mass index; GFR, glomerular filtration rate; ADL, activities of daily living.

of the patients, and 97% continued oral antibiotics for 6 weeks.

With regard to the operation, 24% of the procedures took place in an emergency setting. The majority of patients (82%) underwent complete graft replacement, with 3 (9%) receiving partial graft replacement and the remaining 3 undergoing reconstruction due to mycotic abdominal aneurysm.

During the procedure, 32 patients (94%) were administered heparin before proximal clamping, leaving 2 patients with bleeding conditions who did not receive heparin. In total, 29 (85%) underwent thorough debridement. Most centers rinsed intraoperatively with saline. Antibiotic rinsing was performed with rifampicin in 7 patients (21%). The median operation time was 281 min (240−349).

The bovine pericardial graft was implanted solely in the aorta in 3 patients (9%) and was implanted aorto-bi-iliac in 16 (47%), aorto-bi-femoral in 13 (38%), and iliac-femoral in 2 (6%).

Among the aortic tube grafts, 2 different sizes including 19 × 19 mm (2 patients) and 20 × 20 mm (1 patient) were used. For the aorto-

Table II. Preoperative patient symptoms

	Research group ($N = 34$)
Fever ($T > 38.5^{\circ}C$)[b]	11 (32%)
Tachycardia ($P > 100$/min)[b]	5 (15%)
Signs of infection[b]	30 (88%)
Purulent infection site[b]	22 (65%)
CRP[a]	31.0 (11.5–103.5)
Leukocytes[a]	12.0 (4.9)
Septic[b]	7 (21%)
Primary graft occlusion[b]	2 (6%)

Data are presented as [a]mean/median with the SD/P_{25}-P_{75} between brackets or as [b]N with the percentages between brackets. CRP, C-reactive protein.

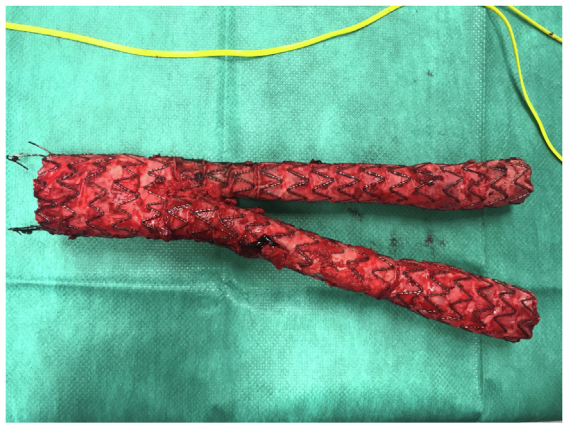

Fig. 1. Intraoperative picture of explanted infected endovascular aneurysm repair.

bi-iliac and aorto-bi-femoral sites, 20 × 10 mm (12 patients) and 18 × 9mm (14 patients) sizes were used. A 16 × 8mm size was used in only 3 patients. At the iliac-femoral site in both cases, 8 × 8 prosthesis were used (Table IV). Figure 2 shows an intraoperative view of a vascular reconstruction with the biomodified bovine pericardial bifurcated conduit. The patient was treated with intravenous antibiotics for 2 weeks and continued oral antibiotics for 6 weeks after discharge. The patient made a full recovery and experienced no complications during follow-up.

Midterm Outcome

The median follow-up period was 350 (195–415) days, with the deceased patients included. Median follow-up among the survival group was 380 (343–438) days. Table V gives an overview of the primary and secondary outcomes.

Reinfection

Reinfection occurred in 3 patients (9%), of which one was an aortic tube with a prosthetic enteric fistula treated endovascularly along with antibiotics, one was an aorto-bi-iliac graft that was explanted and replaced for another biomodified bovine pericardial bifurcated conduit, and one was an aorto-bi-femoral bovine pericardial graft treated with antibiotics only.

Mortality

The overall mortality rate was 29%, including 7 infection-related deaths (21%) and 3 patients who died of causes unrelated to the vascular intervention.

Four patients (12%) passed away during the early postoperative period, within 30 days after the intervention (more specifically, all within 3–11 days after surgery). Of these, 3 had multi-organ failure (MOF), following ischemic colon. The fourth patient was septic and had a cardiac event. Two of these patients had emergency surgeries initially.

The late mortality group comprised 6 patients (18%) who died more than 30 days after the in situ reconstruction. One patient died of an aorto-enteric fistula with massive hemorrhage 48 days after the intervention. Of another 2 patients, one had a fatal cerebrovascular accident and one had a fatal cardiovascular event and deceased after 72 days and 268 days, respectively. Another patient had a duodenal perforation with bleeding, was considered unfit for surgery, and died after 87 days. One patient died due to a gastrointestinal perforation of unknown origin after 128 days; however, due to the patient's condition and liver failure, surgical intervention was considered unfeasible. The last patient in the late mortality group, who died after 217 days, was septic as a result of an infected mesenteric artery stent, with no involvement of the previously placed bovine pericardial graft.

Graft Patency and Amputation

Occlusion of the biomodified bovine pericardial graft was seen among 2 (6%) patients, 1 and 81 days after implementation of the bovine pericardial graft, respectively.

Among the bifurcated grafts, in 2 patients one of the legs of the aorto-bi-femoral biograft was occluded. The first patient had an occlusion after 1 day, probably due to poor outflow (aorto-bi profunda femoral bypass). No intervention was performed, since the patient deceased on short notice. The second patient had an occlusion of the

Table III. Primary material and indication

	Research group ($N = 34$)
Primary (graft) material in situ[a]	
Dacron	23 (68%)
Endovascular graft	8 (24%)
Native vessel (mycotic)	3 (9%)
Indication BioIntegral[a]	
Infected graft replacement	31 (91%)
Mycotic aneurysm	3 (9%)

Data are presented as [a]N with the percentages between brackets.

Table IV. Operation details

	Research group ($N = 34$)
Operation setting (urgent)[b]	8 (24%)
Procedure[b]	
Complete graft replacement	28 (82%)
Partial graft replacement	3 (9%)
Mycotic AAA	3 (9%)
Heparin before proximal clamping[b]	32 (94%)
Debridement[b]	29 (85%)
Antibiotic rinsing[b]	7 (21%)
Implant location[b]	
Aortic	3 (9%)
Aorto-bi-iliac	16 (47%)
Aorto-bi-femoral	13 (38%)
Iliac-femoral	2 (6%)
Operation time[a]	281 (240−349)

Data are presented as [a]mean/median with the SD/P_{25}-P_{75} between brackets or as [b]N with the percentages between brackets. AAA, abdominal aortic aneurysm.

right leg of the bifurcated graft twice, which was successfully treated by thrombectomy twice.

During follow-up, 2 (6%) patients underwent a lower limb amputation, one on account of ongoing ischemia. Another patient had a prior occlusion of the lower leg, already existing before implantation of the biograft, which resulted in an amputation.

DISCUSSION

This prospective clinical study shows that the use of the BioIntegral bovine pericardial graft in patients with a native vascular or (endo)graft infection might be an acceptable alternative in aortoiliac/femoral infections. The quick availability and therapeutic performance make it a feasible option when autologous venous material is unavailable or insufficient, or when time is of the essence.

Similar conclusions have been drawn during the last few decades when using BioIntegral Surgical pericardial grafts to treat endocarditis. A major factor driving infection outcomes for aortic root replacement has been the ''speed to treatment'' and urgency of cases. Elective cases treated early fared better with regard to infection and mortality than emergency cases, which typically present with sepsis and various comorbidities. The basic conclusion is that product availability is a factor in improving outcomes, given its effect on speeding up treatment, both preoperatively and perioperatively.

Yet again, this study confirms the delicate balance between the invasive treatment to cure patients of their infection and the patients' condition. Hence, invasive procedures are not always feasible in this often very ill patient group with many comorbidities. However, reducing mortality and especially morbidity is achievable to some extent by resection of the infected graft, debridement, and vascular reconstruction with either autologous material or a biomodified bovine pericardial graft. Conservative treatment leads to a higher mortality rate, as well as significantly higher morbidity with active ongoing infection frequently uncontrollable by oral antibiotics. Previous studies showed conservative treatment being associated with high mortality, up to 45% during the 5-year follow-up.[27] Nevertheless, we feel treatment of vascular infections should be tailormade, depending on patients' general condition and the severity of the infection.

During the 1-year follow-up, the reinfection rate of the bovine pericardial graft was 9%, a rather good performance of the aortoiliac/femoral grafts in the context of reinfection. In aortic graft infections, the recent guidelines mention that autologous vein reconstruction has the lowest infection rate (0−6%) and the lowest graft occlusion rates (0−9%).[28,29] Although cryopreserved allografts also have shown low reinfection rates, their availability and relatively early degeneration over time is a disadvantage.[12,30,31]

The guidelines also address synthetic grafts being susceptible to (re)infection, as the intended infection-resistant rifampicin-bonded and silver-coated synthetic vascular grafts are still associated with a pooled reinfection rate of 11.5% and 11.0%, respectively.[12,32,33]

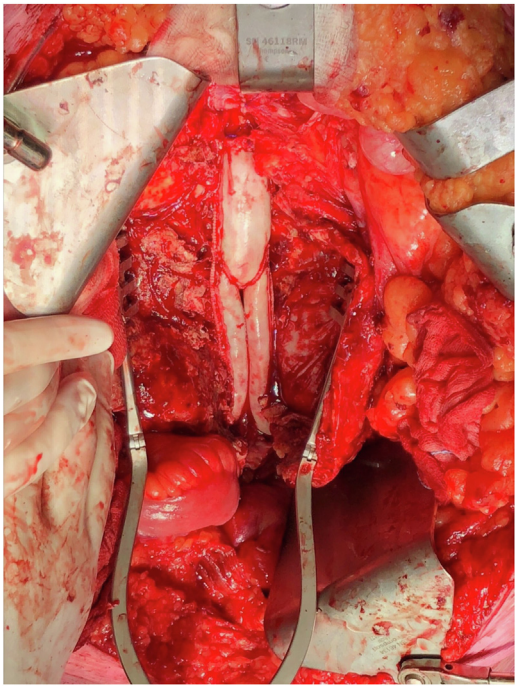

Fig. 2. Intraoperative picture of vascular reconstruction with bovine pericardial bifurcated conduit.

Table V. Outcome at 12 months

	Total cohort ($N = 34$)
Reinfection[b]	3 (9%)
Mortality[b]	10 (29%)
Early mortality	4 (12%)
Late mortality	6 (18%)
Infection-related mortality[b]	7 (21%)
Intervention mortality interval (days)[a]	60.0 (3.8–150.3)
Explantation[b]	1 (3%)
Occlusion[b]	2 (6%)
Amputation[b]	2 (6%)

Data are presented as [a]mean/median with the SD/P_{25}-P_{75} between brackets or as [b]N with the percentages between brackets.

This study shows that the biomodified bovine pericardial graft may have a lower reinfection rate of 9% in aortoiliac/femoral reconstructions. Previous studies, mostly case reports and studies with small sample sizes, assessed hand-sewn xenoprostheses at a back table in the treatment of aortic graft infection. This is one of the first studies to assess ready-to-use bovine pericardial tubes and aorto-biiliac/femoral grafts in a larger patient group.

In this study, the majority of the deaths (7/10, 70%) were due to infection or procedure related, such as MOF. The relatively high mortality rate may be explained by the preoperative condition of the patient and by the severity of aortic infections, which often demanded emergency surgery. The septic state present in 21% of the patients, influenced the perfusion state and resulted in a delicate balance. This was seen in 4 patients who passed away shortly after surgery (procedure-related death); 3 had an ischemic colon with MOF and one died from ongoing sepsis. Two recent studies about autologous vein reconstruction of abdominal aortic vascular graft infection describe late mortality rates up to 40 and 55%.[11,28]

The 12-month patency rate of this study was 94%, which is in line with previous studies reporting graft patency between 81.8% and 100% in aortoiliac/femoral reconstructions with synthetic grafts after infection.[32,34]

During follow-up, no degeneration of the prosthesis was seen. In time, reassessment with a longer follow-up duration is desirable.

The current study has some limitations. Since there is no general consensus about the type of antibiotic given perioperatively and postoperatively, the antimicrobial treatment regimen differed slightly per center. This might be considered a confounding factor. The protocol did advise on the duration but not the kind of antibiotics. To limit other factors involved, a set antimicrobial treatment regimen could contribute to more consistent results.

Furthermore, although being a prospective multicenter study, the relatively small and heterogeneous study population must be taken into account. As a result, all patients who underwent in situ reconstruction with the bovine pericardial graft were included, regardless of the origin of the infection.

In line with the above mentioned, the male sex is dominantly represented in this study. As for the epidemiology of abdominal aortic aneurysms, most studies describe a prevalence up to fourfold less in women than men. Whether this ratio can be exactly extrapolated to the prevalence of VGEI is unknown. However, it is likely to assume that the female gender is under-represented in this study. In addition, it is known that the disease characteristics of women may differ from men, which this study falls short to report.[35]

Assessment during follow-up usually included outpatient visits with CTA scan imaging according to protocol. However, a recent meta-analysis showed higher sensitivity and specificity in diagnosing vascular graft (re)infections with PET/CT

than with CTA, 67% and 63% vs. 95% and 80%, respectively.[36,37] As a consequence, PET/CT should be considered at standardized intervals during follow-up in future prospective studies, especially after 3 months postoperative.

In conclusion, vascular infection often includes an urgent and septic population, as this procedure is seen as the surgical last resort. In patients with prolonged, ongoing infection for whom operating time must be kept as short as possible, no autologous or allograft options are available, and conservative treatment with antibiotics usually is insufficient, a ready to use prosthesis is needed. Although autologous veins remain the first and best choice, they are not always feasible. Reconstruction with a ready to use xenograft has the advantage of immediate availability and could thus be a suitable alternative in an emergency setting. Long-term results will in time demonstrate the clinical employability of the prosthesis.

Overall, the management of vascular infections remains complex, since the patient's general condition, severity of infection, and preferences must be taken into account.

None.

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