Use of Omniflow® II biosynthetic graft for the treatment of vascular graft and endograft infections

Liesker, D.J.; Gareb, B.; Speijers, M.J.; Vorst, J.R. van der; Salemans, P.B.; Nolthenius, R.P.T.; ... ; Saleem, B.

ELSEVIER

Selected Technique

Use of Omniflow® II Biosynthetic Graft for the Treatment of Vascular Graft and Endograft Infections

David J. Liesker,[1] Barzi Gareb,[2] Maarten J. Speijers,[3] Joost R. van der Vorst,[4] Pieter B. Salemans,[5] Rudolf P. Tutein Nolthenius,[6] Clark J. Zeebregts,[1] and Ben R. Saleem,[1] Groningen, Amersfoort, Leiden, Heerlen, and Dordrecht, The Netherlands

Background: Vascular graft/endograft infection is a rare but life-threatening complication of cardiovascular surgery and remains a surgical challenge. Several different graft materials are available for the treatment of vascular graft/endograft infection, each having its own advantages and disadvantages. Biosynthetic vascular grafts have shown low reinfection rates and could be a potential second best after autologous veins in the treatment of vascular graft/endograft infection. Therefore, the aim of our study was to evaluate the efficacy and morbidity of Omniflow® II for the treatment of vascular graft/endograft infection.

Methods: A multicenter retrospective cohort study was performed to evaluate the use of Omniflow® II in the abdominal and peripheral region to treat vascular graft/endograft infection between January 2014 and December 2021. Primary outcome was recurrent vascular graft infection. Secondary outcomes included primary patency, primary assisted patency, secondary patency, all-cause mortality, and major amputation.

Results: Fifty-two patients were included with a median follow-up duration of 26.5 (10.8−54.8) months. Nine (17%) grafts were implanted in intracavitary position and 43 (83%) in peripheral position. Most grafts were used as femoral interposition ($n = 12$, 23%), femoro-femoral crossover ($n = 10$, 19%), femoro-popliteal ($n = 8$, 15%), and aorto-bifemoral ($n = 8$, 15%) graft. Fifteen (29%) grafts were implanted extra-anatomically and 37 (71%) in situ. Eight patients (15%) presented with reinfection during follow-up, most of these patients received an aorto-bifemoral graft ($n = 3$, 38%). Intracavitary vascular grafting had a 33% ($n = 3$) reinfection rate and peripheral grafting 12% ($n = 5$; $P = 0.025$). The estimated primary patencies at 1, 2, and 3 years were 75%, 72%, and 72% for peripherally located grafts and 58% (at all timepoints)

Declarations of interest: The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Funding sources: D.J. Liesker is supported by an unrestricted grant from LeMaitre Vascular, Inc. (63 Second Avenue, Burlington, MA 01803 USA) [grant number: 757426]. The content of the present manuscript is solely the responsibility of the authors and does not represent the views of LeMaitre Vascular, Inc.

[1]*Division of Vascular Surgery, Department of Surgery, University Medical Center Groningen, University of Groningen, Groningen, The Netherlands.*

[2]*Department of Oral and Maxillofacial Surgery, University Medical Center Groningen, University of Groningen, Groningen, The Netherlands.*

[3]*Division of Vascular Surgery, Department of Surgery, Meander Medical Center, Amersfoort, The Netherlands.*

[4]*Division of Vascular Surgery, Department of Surgery, Leiden University Medical Center, Leiden, The Netherlands.*

[5]*Division of Vascular Surgery, Department of Surgery, Zuyderland Medical Center, Heerlen, The Netherlands.*

[6]*Division of Vascular Surgery, Department of Surgery, Albert Schweitzer Hospital, Dordrecht, The Netherlands.*

Correspondence to: David J. Liesker, Division of Vascular Surgery, Department of Surgery, University Medical Center Groningen, PO Box 30.001, 9700 RB, Groningen, The Netherlands; E-mail: d.j.liesker@umcg.nl

Ann Vasc Surg 2023; 97: 410–418
https://doi.org/10.1016/j.avsg.2023.05.020

Manuscript received: February 22, 2023; manuscript accepted: May 15, 2023; published online: 25 May 2023

for intracavitary grafts ($P = 0.815$). Secondary patencies at 1, 2, and 3 years were 77% (at all timepoints) for peripherally located prostheses and 75% (at all timepoints) for intracavitary prostheses ($P = 0.731$). A significantly higher mortality during follow-up was observed in patients who received an intracavitary graft compared to patients with a peripheral graft ($P = 0.003$).
Conclusions: This study highlights the efficacy and safety of the Omniflow® II biosynthetic prosthesis for the treatment of vascular graft/endograft infection, in absence of suitable venous material, with acceptable reinfection, patency, and freedom of amputation prevalences, especially in replacing peripheral vascular graft/endograft infection. However, a control group with either venous reconstruction or another alternative graft is needed to make firmer conclusions.

INTRODUCTION

Vascular graft and endograft infection (VGEI) is a rare but life-threatening complication of cardiovascular surgery. It remains a surgical challenge due to a significant risk of recurrent infection with associated high morbidity and mortality.[1,2] Removal of the infected vascular graft material, extensive debridement, in situ reconstruction with infection resistant material, and (targeted) antibiotics is the first choice treatment of vascular graft infection.[1] Several graft materials are available for the treatment of VGEI including autologous veins, cryopreserved allografts, synthetic grafts, biological xenografts, and biosynthetic materials, such as Omniflow® II prosthesis. Each of these materials has its own set of advantages and disadvantages. Autologous veins are commonly used because of their moderate resistance to reinfection and desirable patency.[3,4] However, veins are not always of suitable size or quality, nor readily available in emergency setting. The main advantage of cryopreserved allografts is that they have a lower infection rate than synthetic prostheses. Nevertheless, long-term outcomes are suboptimal with allograft degeneration and high reintervention rates.[5,6] The major benefit of synthetic grafts is that they are readily available. The main drawback of these grafts is the presumed higher reinfection rates compared to venous material and cryopreserved allografts.[1] Biosynthetic grafts have shown good late graft patency and low postoperative infection rates when used as elective bypass material.[7–9] Low infection rates could make biosynthetic grafts a potential alternative in the treatment of VGEI in the absence of autologous material. However, literature on biosynthetic prostheses in the treatment of VGEI in the abdominal and peripheral region is scarce.[7,10,11] In 2012, Töpel et al. found that biosynthetic grafts seem to be a possible alternative to venous reconstruction to replace infected infrainguinal grafts.[10] This conclusion was based on 7 patients only. More recently, in 2022, Caradu et al. published acceptable results of using Omniflow® II in a septic context (including VGEI) when autologous veins were unavailable.[11] Although the results were promising, their cohort only consisted of 29 patients. Therefore, the aim of this study was to evaluate the efficacy and morbidity of Omniflow® II as a treatment for VGEI in the absence of venous material in 5 high-volume vascular surgery centers in the Netherlands.

MATERIAL AND METHODS

Study Design

All consecutive patients who underwent treatment for abdominal aortic and peripheral VGEI using an Omniflow® II graft between January 2014 and December 2021 at 5 hospitals in the Netherlands (University Medical Center Groningen, Leiden University Medical Center, Zuyderland Medical Center, Albert Schweitzer Hospital, and Meander Medical Center) were included in this study. VGEI was defined according the Management of Aortic Graft Infection Collaboration (MAGIC) criteria.[12]

The Institutional Review Board approved dispensation in accordance with Dutch law on patient-based medical research obligations (registration no. METc 2021/494). Therefore, informed consent was not required. Local approval at each medical center was obtained. All patient related data were processed anonymously and stored electronically in agreement with the Declaration of Helsinki—Ethical principles for medical research involving human subjects.[13]

Patient Characteristics and Definitions

Baseline characteristics were obtained from the electronic patient file including age at time of surgery, sex, body mass index, tobacco use, hypertension, dyslipidemia, diabetes mellitus (type I or II), and cardiac-, pulmonary-, and renal disease. Tobacco use was defined as current use or less than 1 year of abstinence. Hypertension, dyslipidemia, cardiac-, pulmonary-, and renal disease were

Fig. 1. A bifurcated bypass created by spatulating and anastomosing 2 8-mm tubular Omniflow® II grafts.

classified by the Society for Vascular Surgery (SVS) system (class 0−3) according to the Ad Hoc Committee on Reporting Standard.[14] These comorbidities were scored positive if the status was ≥1. American Society of Anesthesiologists (ASA) scores were noted.[15] Furthermore, preoperative characteristics, intraoperative characteristics, and postoperative (short-term adverse events, <30 day) outcomes were collected. The short-term (<30 days postoperative) adverse events included graft occlusion, (all-cause) mortality, wound infection, transient ischemic attack or cerebrovascular accident, urinary tract infection, cardiac complications (defined as myocardial infarction, angina pectoris, arrhythmia, or congestive heart failure), delirium, and hematoma (requiring surgical evacuation or arterial repair).

Technical Aspects

The Omniflow® II vascular prosthesis (LeMaitre Vascular, Inc., 63 Second Avenue Burlington, MA 01803, USA) is a denatured ovine collagen prosthesis.[16] It is made of a grown ovine collagen tube that is induced by subcutaneously implanting a polyester mesh endoskeleton into a sheep. Prior to usage, a specific rinsing procedure is performed, as prescribed by the manufacturer.[16] Manipulation of the graft was minimized. In case of intracavitary positioning (aortic, aorto-bifemoral, or aorto-biiliac), a (bifurcated) bypass was created by the surgeon by spatulating and anastomosing 2 8-mm tubular Omniflow® II grafts (Fig. 1). In case of large diameters the graft could be cut obliquely to prevent discrepancy.

Outcomes

The primary outcome of this study was recurrent vascular graft infection (based on the MAGIC-criteria). Secondary outcomes were primary patency, primary assisted patency, secondary patency, all-cause mortality, and major amputation during the total postoperative follow-up period (from surgery to long-term follow-up). Primary, primary assisted, and secondary patency were defined according to the reporting standards of the SVS.[14,17] Major amputation was defined as transtibial amputation, knee disarticulation, or transfemoral amputation.

Statistical Analysis

Distribution of continuous data were checked visually and supplemented by the Shapiro-Wilk test. Non-normally distributed continuous variables were reported as median and interquartile range (first quartile-third quartile). Categorical data were reported in absolute numbers with according percentages. Kaplan−Meier survival curves were plotted to visualize the survival of primary and secondary outcomes. Subgroups were compared using the Log rank test. Statistical analysis was performed in R, version 4.0.5 (R Foundation for Statical Computing, Vienna, Austria), using the *survival*, *survminer*-, and *ggplot2*-packages. In all analyses, $P < 0.05$ was considered statistically significant.

RESULTS

Patient Characteristics

A total of 52 patients were included in this study. The median age was 71.0 (62.0−75.0) years and 32 (62%) patients were male. The prevalence of comorbidities at baseline was as follows: 83% hypertension, 87% dyslipidemia, and 33% diabetes mellitus (type I or II). The majority of patients (64%) had an ASA-score of III. Other comorbidities are shown in Table I.

Table I. Patient characteristics

Patient characteristics	*N* (%) or median (P25-P75)
Number of patients	52
Age in years	71.0 (62.0−75.0)
Sex (males)	32 (62)
BMI in kg/m^2	25.5 (23.1−29.4)
Tobacco use	24 (46)
Hypertension	43 (83)
Dyslipidemia	45 (87)
Diabetes mellitus	17 (33)
Cerebrovascular disease	14 (27)
Cardiac disease	26 (50)
Pulmonary disease	19 (37)
Renal disease	12 (23)
ASA-score	
I	0 (0)
II	8 (15)
III	33 (64)
IV	10 (19)
V	1 (2)

P25, first quartile, P75, third quartile, BMI, body mass index.

Preoperative Data

Sixty-four percent of patients were on preoperative antiplatelet therapy, 52% received anticoagulation (of which 22 patients [81%] used a vitamin K antagonist and 5 patients [19%] used a direct oral anticoagulant), and 65% received antibiotics (other than standard perioperative antibiotic prophylaxis) (Table II). Thirty-one percent of patients underwent acute surgery, 42% underwent semi-elective surgery (<2 weeks), and 27% underwent elective surgery. Laboratory findings included a median hemoglobin level of 7.0 (6.3−8.2) mmol/L, a median white blood cell count of 8.8 × 10^9/L (7.4−12.1), and a median CRP level of 30.0 (9.8−107.8) mg/L.

Intraoperative Data

The median intervention time was 297.5 (211.0−420.0) min and infected prosthetic material was completely removed in 48% of the cases (Table II). Intraoperative cultures were taken in 90% of operations, of which 35 (74%) were positive. Nine (17%) prostheses were implanted in intracavitary position and 43 (83%) in peripheral position. In 3 patients with an intracavitary graft, an aorto-enteric fistula was repaired during index surgery. Partial removal of the infected graft was the case for 2 intracavitary and 24 peripheral grafts. Forty-five patients were treated for a graft infection, 5 patients for an endograft infection, and 2 patients for a combination of graft and endograft infection. The most common locations of the vascular reconstruction with Omniflow® II were aorto-bifemoral (n = 8, 15%), femoral interposition (n = 12, 23%), femoro-femoral crossover (n = 10, 19%), and femoro-popliteal (n = 8, 15%; 1 above knee and 7 below knee distal anastomosis). Other graft positions are shown in Table II.

Postoperative Data

Ninety-eight percent of patients received postoperative antibiotic therapy. Twelve (23%) patients received (life-long) antibiotic suppression therapy until failure. The other patients received antibiotic therapy for median 42 (14−42) days. The median length of hospital stay was 16 (10−27) days. Median follow-up duration was 27 (11−55) months (Table II).

Short-Term Adverse Events (<30 Days)

The most common short-term adverse event was occlusion (10%) of which the following bypasses were affected: axillo-femoral (n = 1), aorto-bifemoral (n = 1), ilio-femoral (n = 1), femoro-femoral crossover bypass (n = 1), and femoro-popliteal (below the knee) (n = 1). Two patients underwent a thrombectomy, 1 patient underwent graft replacement surgery, and 1 patient underwent endarterectomy with patch angioplasty with a bovine patch. The last patient with an occluded reconstruction (femoropopliteal) did not undergo a surgical procedure, because this patient had too few symptoms compared to the risks of the surgical procedure.

The second most common 30-days adverse event was mortality (8%). In the 30-day mortality group, 1 patient died due to sepsis after receiving an axillo-femoral prosthesis. The other 3 patients in this group all got aorto-bifemoral reconstructions. The first patient with an infected aorto-bifemoral

Table II. Preoperative, intraoperative, and postoperative characteristics

Characteristic	*N* (%) or median (P25-P75)
Preoperative	
Antiplatelet therapy	34 (64)
Anticoagulation	27 (52)
Preoperative antibiotic therapy[a]	34 (65)
Blood cultures	
Cultures taken (yes)	35 (67)
Negative	17 (49)
Positive	18 (51)
Setting	
Acute (48 hr)	16 (31)
Semi-elective (<2 weeks)	22 (42)
Elective	14 (27)
Hemoglobin (mmol/l)	7.0 (6.3−8.2)
White blood cell count (10^9/L)	8.8 (7.4−12.1)
C-reactive protein (mg/L)	30.0 (9.8−107.8)
Intraoperative	
Intervention time (min)	297.5 (211.0−420.0)
Complete removal of (infected) prosthetic material	25 (48)
Intraoperative cultures	
Cultures taken (yes)	47 (90)
Negative	12 (26)
Positive	35 (74)
Position of reconstructive bypass	
Intracavitary	
Aorto-biiliac	1 (2)
Aorto-bifemoral	8 (15)
Peripheral	
Axillo-femoral	1 (2)
Ilio-femoral crossover	1 (2)
Ilio-femoral	6 (12)
Obturator bypass	3 (6)
Femoral interposition	12 (23)
Femoro-femoral crossover	10 (19)
Femoro-popliteal	8 (15)
Below knee	7 (88)
Above knee	1 (13)
Femoro-crural	2 (4)
Diameter	
6 mm	20 (39)
8 mm	25 (48)
Missing	7 (13)
Postoperative	
Antibiotic therapy	51 (98)
Length of hospital stay (days)	16 (10−27)
Median follow-up (months)	27 (11−55)

P25, first quartile, P75, third quartile.
[a]Other than standard perioperative regime.

reconstruction presented with rectal blood loss caused by an aorto-enteric fistula. This patient underwent replacement surgery and repair of the fistula. However, postoperatively, the patient deteriorated clinically and biochemically and a hemorrhagic shock without further treatment options was diagnosed. The other 2 patients died due to intestinal ischemia. One patient underwent a relaparotomy with resection of an ischemic sigmoid 4 days postoperatively. An explorative relaparotomy was performed 2 days later because of deterioration. Free fluid was observed and rinsing and drainage was performed. However, the patient died, 2 days postoperatively. The other patient had abdominal pain 2 days postoperatively and underwent a sigmoidoscopy where transmural ischemia was seen on sigmoidoscopy. At relaparotomy there was ischemia of the entire sigmoid, from 60 cm after ligament of Treitz including the ileocecal angle, and multiple parts of the jejunum and ileum. A sigmoid resection was performed and 3 parts of small intestine were removed. Parts of the remaining small intestine were still ischemic. A relaparotomy was done 1 day later and the ischemia had increased. The patient died the same day. Wound infection was also observed in 8% of the patients. All wound infections were treated with antibiotic therapy, incision and drainage. One of these patients developed a recurrent vascular graft infection (Table III).

Table III. Postoperative short-term adverse outcomes (<30 days)

Characteristic	*N* (%)
Graft occlusion	5 (10)
Mortality	4 (8)
Wound infection	4 (8)
TIA or CVA	3 (6)
Urinary tract infection	3 (6)
Cardiac complication[a]	2 (4)
Delirium	2 (4)
Hematoma[b]	1 (2)

TIA, transient ischemic attack; CVA, cerebrovascular accident.
[a]Defined as myocardial infarction, angina pectoris, arrhythmia, or congestive heart failure.
[b]Society of Vascular Surgery (SVS) Reporting standards: hematoma class II-III.

Recurrent Vascular Graft Infection

Eight patients (15%) got a reinfection of the vascular graft (Fig. 2A and Supplemental Table I). In 4 (50%) of these patients, vascular graft material was not completely removed at time of index surgery (i.e. initial VGEI treatment with Omniflow® II). The estimated freedom of reinfection was 87%, 83%, and 80% at 1, 2, and 3 years, respectively. The grafts of these patients were located in the

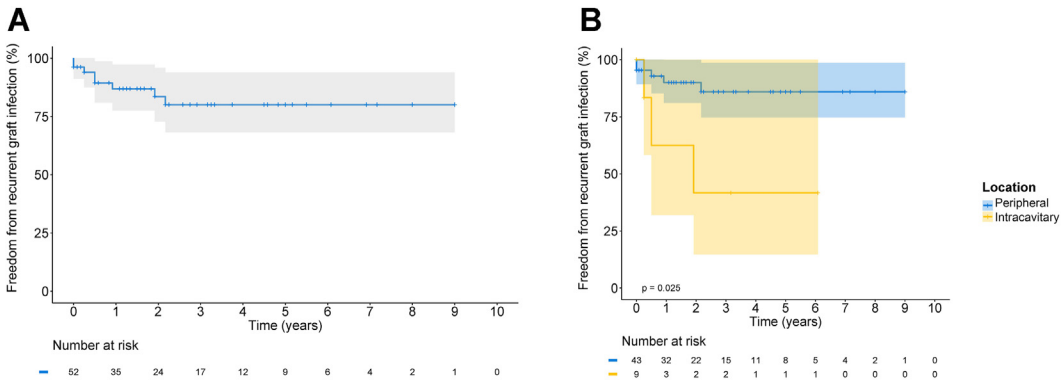

Fig. 2. Occurrence of recurrent graft infection for patients treated with Omniflow® II (A) and recurrent graft infection stratified by position (intracavitary versus peripheral) (B).

following positions: aorto-bifemoral ($n = 3$), ilio-femoral ($n = 1$), femoral interposition ($n = 2$), and femoro-femoral ($n = 2$). Thirty-three percent ($n = 3$) of grafts in intracavitary position and 12% ($n = 5$) of grafts in peripheral position got a reinfection ($P = 0.025$, Fig. 2B). In the intracavitary group, the cause of initial VGEI (at index surgery) was an aorto-enteric fistula in 1 patient and unknown in the other patients. Blood cultures were taken in 7 cases, of which 2 were positive. The first culture contained *Enterococcus faecium*, *Bacteroides fragilis* and *Eikenella corrodens* and the second culture contained *Granulicatella adiacens* and *Fusobacterium nucleatum*. All patients were treated with antibiotic therapy. Five (63%) patients underwent a reintervention. Four patients got complete removal of the Omniflow® II and 1 patient got an aorto-enteric fistula removed. The last patient underwent partial replacement of the prosthesis (infected area based on imaging) and repair of the aorto-enteric fistula. One patient underwent removal without replacement of a new prosthesis, because of a pre-existent occlusion. The other patients underwent in situ repair with an Omniflow® II bypass, a venous (deep femoral vein) graft, and a bovine pericardial prosthesis (BioIntegral Surgical No-React), respectively. Infected material was obtained and cultured during all procedures. All cultures were positive. A mortality of 38% ($n = 3$) was observed in patients with a reinfection. Two of these patients were treated surgically and 1 patient with antibiotic therapy alone. The first patient died within 1 week after reintervention (partial graft replacement and aorto-enteric fistula removal), most likely because of a persistent bleed (hemodynamic instability with a Hb decrease). The other patient died 7 months after replacement surgery (with a venous graft) in a palliative setting because of progression of peripheral arterial disease and infection. The conservatively treated patient died 3 years after the diagnosis of VGEI due to cardiopulmonary disease.

Primary (Assisted) and Secondary Patency

The estimated primary patencies of the total group at 1, 2 and 3 years were 73%, 71%, and 71%, respectively (Fig. 3A). Primary assisted patency at 1, 2, and 3 years were 73% (Fig. 3B). The estimated secondary patencies at 1, 2, and 3 years were 77% (Fig. 3C). The estimated primary patencies at 1, 2, and 3 years were 75%, 72%, and 72% for peripherally located grafts and 58% (at all timepoints) for intracavitary grafts, respectively. Primary assisted patencies at 1, 2, and 3 years were 75% (at all timepoints) for peripherally located prostheses and 58% (at all timepoints) for intracavitary prostheses. Secondary patencies at 1, 2, and 3 years were 77% (at all timepoints) for peripherally located prostheses and 75% (at all timepoints) for intracavitary prostheses. No significant differences were observed between intracavitary and peripheral Omniflow® II bypass grafts regarding primary patency ($P = 0.815$), primary assisted patency ($P = 0.763$), and secondary patency ($P = 0.731$).

Mortality and Major Amputation

Fourteen (27%) patients died during the follow-up period (Supplemental Fig. 1A). The 1, 2, and 3 year estimated mortality rates in the total group were 82%, 79%, and 76%, respectively. The estimated mortality at 1, 2, and 3 years were 90%, 87%, and 82% for peripherally located grafts and 44% (at all timepoints) for intracavitary grafts, respectively. The most common reasons for

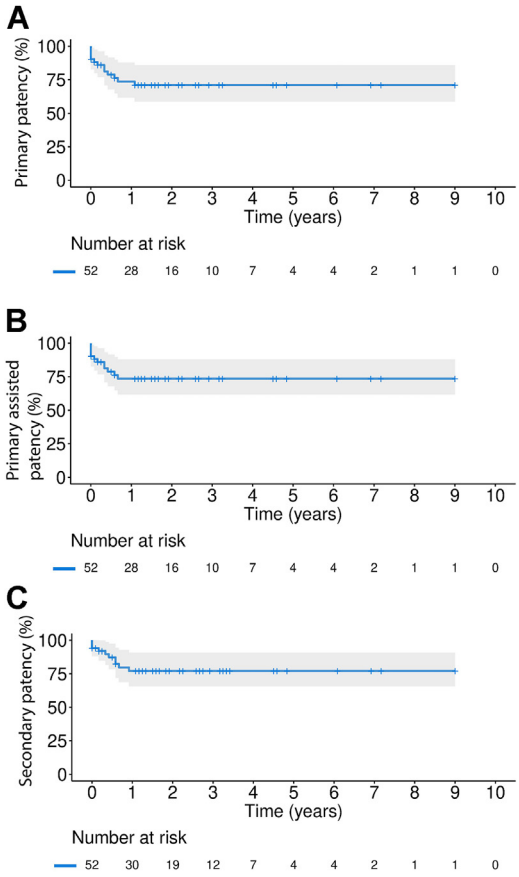

Fig. 3. Primary patency (A), primary assisted patency (B), and secondary patency (C) of Omniflow® II used for treatment of vascular graft and endograft infection.

mortality were malignancy (21%), intestinal ischemia (14%), bleeding from an aorto-enteric fistula (14%), and progression of peripheral arterial disease (14%). Six (43%) of the patients who died had an aorto-biiliac ($n = 1$) or an aorto-bifemoral prosthesis ($n = 5$). A significantly higher mortality was observed in patients who received an intracavitary Omniflow® II graft versus patients who received a graft peripherally ($P = 0.003$, Supplemental Fig. 1B). The ASA-scores of patients who received an intracavitary Omniflow® II were significantly higher than the ASA-scores of patients with a peripheral Omniflow® II ($P = 0.006$). Five patients (55%) with an intracavitary Omniflow® II and none of the patients with a peripheral Omniflow® II had an ASA-score $\geq$ IV (Supplemental Table II). Overall, 6 (12%) major amputations were required, of which 4 were transfemoral and 2 were transtibial. None of the patients with an intracavitary Omniflow® II underwent an amputation. The 1 and 3 year estimated freedom of amputation were 89% and 87%, respectively (Supplemental Fig. 2).

DISCUSSION

This multicenter cohort study includes the largest cohort of patients treated with Omniflow® II biosynthetic bypass for VGEI. It shows the efficacy and safety of the Omniflow® construct when an autologous venous reconstruction is unfeasible.

In the current study, the reinfection-free survival (87% and 80% at 1 and 3 years, respectively) was comparable to a recently published French multicenter study about the use of Omniflow® II in a septic field.[11] Caradu et al. found a reinfection-free survival of 86% at 1 and 3 years. Reinfections were most common in intracavitary prostheses, followed by peripherally located prostheses in our cohort. Interestingly, no reinfections were observed in femoro-popliteal reconstruction. Another study focusing on replacement surgery for infected peripheral grafts also found no reinfections.[18] These lower reinfection occurrence could possibly be related to the rapid graft incorporation after implantation in the host.[19] A study performed by Matic et al. examined infected femoropopliteal grafts that were replaced with silver-coated prostheses and found a reinfection occurrence of 19%.[20] Though cryopreserved allografts have shown lower reinfection rates than prosthetic or biosynthetic grafts, degeneration of the allograft can occur, leading to devastating complications (i.e. aneurysm formation and rupture).[21–23] Another disadvantage of cryopreserved allografts is their limited availability. Previous studies on various graft materials used for aortic graft infection have shown lower reinfection than we observed.[1,24–26] These studies found reinfection occurrences of 9%, 11%, and up to 16% for cryopreserved allografts, silver coated grafts, and bovine pericardial grafts, respectively.[1,24] El Beyrouti et al. found a reinfection prevalence of 6.3% using Omniflow® II in patients with intracavitary reconstruction with a mean follow-up of 29 ± 17 months. However, their study included patients with a high risk of vascular graft infection, in addition to patients with an already diagnosed VGEI.[25] Our group included a large amount of patients being critically ill, with 55% of the patients having an ASA-score $\geq$ IV, which may be an explanation for the higher reinfection occurrence.

The primary patency we observed was in line with prior studies on Omniflow® II and alternative grafts. One study described a primary patency prevalence of 66% at 3 years in peripherally placed Omniflow® II grafts that were used in septic context.[11] Another study found a primary patency prevalence of 57% in cryopreserved allografts in a peripheral position 3 years postsurgery.[22] In

addition to the patency observed in our cohort, freedom of (major) amputation prevalences were excellent: 89% at 1 year and 87% at 3 years. Our results are comparable to existing literature referred to above, with freedom of major amputation prevalences of 84% and 87%.[11,22]

Limitations

This study has its limitations. First, the retrospective design of our study limits the conclusions to be hypothesis generating. Another limitation is the heterogeneity of our cohort, including differences in medical (i.e., antibiotic therapies) and surgical treatment (i.e., different anatomical positions). Furthermore, the lack of a control group reduces the power of the conclusions on this graft. However, literature on the use of Omniflow® II bypass for the treatment of VGEI is scarce and to our knowledge, to date, this multicenter study represents the largest study of its kind.

CONCLUSION

This study highlights the efficacy of the Omniflow® II biosynthetic prosthesis for the treatment of VGEI as an ''off-the-shelf'' prosthesis, in absence of a suitable vein. It has shown acceptable reinfection-, patency-, and freedom of amputation prevalences, especially for treatment of peripheral VGEI. More research is needed to evaluate the use of Omniflow® II for intracavitary VGEI and to evaluate the outcomes of Omniflow® II compared to other materials (i.e., autologous veins, cryopreserved allografts, or synthetic prostheses).

SUPPLEMENTARY DATA

Supplementary data related to this article can be found at https://doi.org/10.1016/j.avsg.2023.05.020.

REFERENCES

1. Chakfé N, Diener H, Lejay A, et al. Editor's Choice — European Society for Vascular Surgery (ESVS) 2020 Clinical Practice Guidelines on the Management of Vascular Graft and Endograft Infections. Eur J Vasc Endovasc Surg 2020;59:339–84.
2. Wilson WR, Bower TC, Creager MA, et al. Vascular graft infections, mycotic aneurysms, and endovascular infections: a Scientific Statement from the American Heart Association. Circulation 2016;134:e412–60.
3. Dorweiler B, Neufang A, Chaban R, et al. Use and durability of femoral vein for autologous reconstruction with infection of the aortoiliofemoral axis. J Vasc Surg 2014;59:675–83.
4. Ehsan O, Gibbons CP. A 10-year experience of using femoropopliteal vein for Re-vascularisation in graft and arterial infections. Eur J Vasc Endovasc Surg 2009;38:172–9.
5. Lejay A, Delay C, Girsowicz E, et al. Cryopreserved cadaveric arterial allograft for arterial reconstruction in patients with prosthetic infection. Eur J Vasc Endovasc Surg 2017;54:636–44.
6. Antonopoulos CN, Papakonstantinou NA, Hardy D, et al. Editor's choice — cryopreserved allografts for arterial reconstruction after aorto-Iliac infection: a systematic review and meta-analysis. Eur J Vasc Endovasc Surg 2019;58:120–8.
7. Koch G, Gutschi S, Pascher O, et al. Analysis of 274 Omniflow vascular prosthesis over an eight-year period. ANZ J Surg 1997;67:637–9.
8. Socrate AM, Spampinato B, Zuccon G, et al. Outcomes of biosynthetic vascular graft for infrainguinal femoropopliteal and femoro-distal revascularization. J Cardiovasc Surg (Torino) 2021;62:369–76.
9. Neufang A, Duenschede F, Espinola-Klein C, et al. Contemporary results with the biosynthetic glutaraldehyde denatured ovine collagen graft (Omniflow II) in femoropopliteal position. J Vasc Surg 2020;71:1630–43.
10. Töpel I, Betz T, Uhl C, et al. Use of biosynthetic prosthesis (Omniflow II®) to replace infected infrainguinal prosthetic grafts - first results. Vasa 2012;41:215–20.
11. Caradu C, Brunet C, Spampinato B, et al. Contemporary results with the biosynthetic glutaraldehyde denatured ovine collagen graft (Omniflow II) in lower extremity arterial revascularization in a septic context. Ann Vasc Surg 2022;85:22–31.
12. Anagnostopoulos A, Mayer F, Ledergerber B, et al. Editor's choice — validation of the Management of aortic graft infection Collaboration (MAGIC) criteria for the diagnosis of vascular graft/endograft infection: results from the Prospective vascular graft cohort study. Eur J Vasc Endovasc Surg 2021;62:251–7.
13. WMA declaration of Helsinki - ethical principles for medical research involving human subjects. Available at: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles for-medical-research-involving-human-subjects/. Accessed January 3, 2022.
14. Rutherford RB, Baker JD, Ernst C, et al. Recommended standards for reports dealing with lower extremity ischemia: revised version. J Vasc Surg 1997;26:517–38.
15. Saklad M. Grading of patients for surgical procedures. Anesthesiology 1941;2:281–4.
16. LeMaitre. Omniflow II vascular prosthesis. Available at: https://www.lemaitre.com/products/omniflow-ii-vascular-prosthesis. Accessed December 5, 2022.
17. Stoner MC, Calligaro KD, Chaer RA, et al. Reporting standards of the Society for Vascular Surgery for endovascular treatment of chronic lower extremity peripheral artery disease. J Vasc Surg 2016;64:e1–21.
18. Wiltberger G, Matia I, Schmelzle M, et al. Mid- and long-term results after replacement of infected peripheral vascular prosthetic grafts with biosynthetic collagen prosthesis. J Cardiovasc Surg (Torino) 2014;55:693–8.
19. Menger M, Hammersen F, Messmer K. In Vivo assessment of neovascularization and incorporation of prosthetic vascular biografts. Thorac Cardiovasc Surg 1992;40:19–25.
20. Matic P, Tanaskovic S, Babic S, et al. In situ revascularisation for femoropopliteal graft infection: ten years of experience with silver grafts. Vascular 2014;22:323–7.

21. Minga Lowampa E, Holemans C, Stiennon L, et al. Late fate of cryopreserved arterial allografts. Eur J Vasc Endovasc Surg 2016;52:696−702.
22. Castier Y, Paraskevas N, Maury J-M, et al. Cryopreserved arterial allograft reconstruction for infected peripheral bypass. Ann Vasc Surg 2010;24:994−9.
23. Brown KE, Heyer K, Rodriguez H, et al. Arterial reconstruction with cryopreserved human allografts in the setting of infection: a single-center experience with midterm follow-up. J Vasc Surg 2009;49:660−6.
24. Batt M, Feugier P, Camou F, et al. A Meta-analysis of outcomes after in situ reconstructions for aortic graft infection. Angiology 2018;69:370−9.
25. El Beyrouti H, Izzat MB, Kornberger A, et al. Ovine biosynthetic grafts for aortoiliac reconstructions in non-sterile operative fields. Thorac Cardiovasc Surg 2022;70:645−51.
26. Keschenau PR, Gombert A, Barbati ME, et al. Xenogeneic materials for the surgical treatment of aortic infections. J Thorac Dis 2021;13:3021−32.