

A systematic review and meta-analysis of the use of the Omniflow II biosynthetic graft for aortic reconstruction

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ABSTRACT

Objective: Despite the improvements in xenogeneic grafts and surgical techniques, management of aortic graft infection has remained challenging. The optimal graft material has remained controversial, with high rates of reinfection using prosthetic grafts and a limited time for venous harvest in an emergent setting. Recent studies have highlighted an increase in the use of Omniflow II biosynthetic vascular grafts (LeMaitre Vascular, Burlington, MA) for aortic reconstruction. The primary aim of the present study was to review the key outcomes for the Omniflow II graft in terms of reinfection and complications.

Methods: The National Healthcare Service healthcare databases advanced search function was used to search nine databases for the search term "Omniflow." The present study complied with the PRISMA (preferred reporting items for systematic review and meta-analysis) statement. Eligible studies related to aortic graft infection or in situ aortic reconstruction were selected in accordance with prespecified eligibility criteria and included for review. Data on the surgical technique, comorbidities, graft reinfection, mortality, and complications were combined. The data were analyzed using Stata/MP, version 17 (StataCorp, College Station, TX), and the probabilities were pooled using a DerSimonian and Laird random effects model with Freeman-Tukey arcsine transformation.

Results: Six studies with 60 patients (44 men; age range, 29-89 years) were included. Of the 60 patients, 25 had undergone surgical reconstruction because of early graft infection (<4 months after the index procedure), 24 for late graft infection, and 3 because of mycotic aneurysms. Eight high-risk patients had undergone surgical reconstruction for prevention of an initial graft infection. *Staphylococcus aureus*, *Escherichia coli*, and *S. epidermis* were the most common organisms. Early mortality was 8.83% (95% confidence interval [CI], 1.12%-20.53%), and late mortality was 18.49% (95% CI, 5.51%-35.34%). Follow-up varied from 9 months to 2 years. No graft rupture or graft degeneration had occurred during follow-up. However, 6.2% (95% CI, 0.39%-15.81%) had experienced early graft occlusion, and 3.83% (95% CI, 0.00%-16.34%) had developed early graft stenosis. Two cases of postoperative reinfection were reported. The freedom from reinfection was 97.71% (95% CI, 87.94%-100.00%).

Conclusions: Use of the Omniflow II graft for aortic reconstruction is a feasible alternative with acceptable mortality and low reinfection rates. However, there is a risk of limb occlusion. Although these studies were of low quality, the Omniflow II graft shows promise in this difficult patient cohort, especially when bifurcated reconstruction is required. (*J Vasc Surg* 2023;77:964-70.)

Keywords: Aorta; Biosynthetic graft; Omniflow; Revascularization

Advances in surgical techniques and grafts and improvements in perioperative management have led to better surgical outcomes after aortic graft infection. Current evidence favors aortic reconstruction rather than

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ligation and axillofemoral bypass for both native infection (mycotic aneurysms) and aortic graft infections.¹ Despite the improvements in outcomes, graft reinfection has remained a serious clinical concern. Graft infections are associated with a risk of morbidity and mortality as a result of sepsis, anastomotic rupture, and septic embolization.

In situ reconstruction is a treatment option for graft infection and can be undertaken using a variety of grafts, including autologous veins, cryopreserved allografts, rifampicin-bonded or silver-coated synthetic grafts, and, more recently, xenogeneic grafts. The optimal graft material for aortic reconstruction has been debated in the literature. An ideal graft should be readily available, resistant to infection, and cause no untoward harm to the patient. At present, one option is the use of autologous vein grafts, which has been associated with low reinfection rates (0%-6%).²

However, the use of autologous vein grafts can lead to venous insufficiency, and the need for venous harvesting means these grafts are unsuitable for urgent and emergent cases.^{3,4}

The use of cadaveric grafts means difficulty with access and can result in long-term graft degeneration.⁵ Rifampicin-bonded grafts can lead to rifampicin resistance, and both rifampicin-bonded and silver-impregnated grafts use prosthetic material and have had higher reported reinfection rates ($\leq 11.5\%$ and $\leq 11\%$, respectively).⁶ The availability of xenogeneic material such as bovine and ovine has led to a recent increase in the use of these grafts for aortic reconstruction.

The biosynthetic Omniflow II graft (LeMaitre Vascular, Burlington, MA), which consists of an ovine collagen matrix on a polyester mesh, is a promising alternative for aortic reconstruction, especially when bifurcated reconstruction is required. The Omniflow II synthetic graft is readily available and easily adapted.⁷ It can be modified to produce a bifurcated graft and can be used in the iliac or femoral regions as required. Although the Omniflow II graft is a viable alternative for aortic reconstruction, limited data are available on the reinfection rates and postoperative outcomes. The aim of the present study was to review the outcomes with the Omniflow II graft for aortic reconstruction in patients with mycotic aneurysms, with infected aortic grafts, and at risk of graft infection.

METHODS

The National Healthcare Service healthcare databases advanced search function was used to conduct a literature search for the term "Omniflow" for studies reported from June 1989 to February 2022. The search adhered to the PRISMA (preferred reporting items for systematic review and meta-analysis) statement.⁸ Databases searched included AMED (Allied and Complementary Medicine Database), BMI, CINAHL (Cumulative Index to Nursing and Allied Health Literature), EMBASE, EMCARE, MEDLINE, and PubMed. No filters or limits were used. Duplicate reports were removed, and the results were exported into Excel (Microsoft Corp, Redmond, WA). The studies were examined by title and abstract and selected in accordance with the eligibility criteria. The studies were selected if they had met the following eligibility criteria:

- Randomized control trial, cohort study, case series, or case study
- Receipt of an aortic graft to treat an aortic infection
- Some, if not all, patients involved in the study had received the Omniflow II synthetic graft
- Follow-up outcomes had included infection and/or early and late postoperative outcomes

Studies that had examined the use of Omniflow grafts for peripheral arterial bypass were excluded. The studies that had not met the inclusion criteria were excluded. The reports of all studies that remained were successfully retrieved. Two of us (N.E.-D. and A.W.-J.) independently conducted the literature search and extracted the data. Any disagreements were discussed and resolved by consensus with a third party (P.W.S.).

Studies that had included multiple graft types were included if an Omniflow graft had been used for any component of the repair. The individual patient data were reviewed to exclude those patients who had received prosthetic- or bovine-only grafts.

The primary outcomes were (1) graft reinfection (including microorganisms detected during infection); (2) graft rupture; (3) graft occlusion; and (4) graft degeneration. The secondary outcomes included (1) early and late postoperative complications; (2) length of hospital stay and follow-up; and (3) mortality. The outcomes were tabulated and the data grouped manually for each intervention for comparison. For studies in which the period for early and late complications had not been specified, <30 days and >30 days postoperatively, respectively, were assumed.^{9,10}

No automation tools were used to assess the risk of bias in the included studies owing to the number of studies available for inclusion and the lack of comparative data. The quality and risk of bias was assessed independently by two of us (N.E.-D. and A.W.-J.) using the Joanna Briggs Institute critical appraisal tool. Any disagreements were discussed and resolved by discussion with a third party (P.W.S.).

Statistical analysis was performed using Stata/MP, version 17 (StataCorp, College Station, TX). Probabilities were pooled using a DerSimonian and Laird random effects model with Freeman-Tukey arcsine transformation. Individual case reports were not included in the pooled data; however, their data have been reported in the text and tables as appropriate.

RESULTS

Our search yielded 194 studies. Of the 194 studies found, 6, with a total of 60 patients (44 men; age range, 29-89 years), had met the eligibility criteria and were included in the present systematic review (Fig 1). The characteristics of the six studies are presented in [Supplementary Table 1](#) (online only).

Overall, 60 patients had received the Omniflow II synthetic graft (LeMaitre Vascular), 12 of whom had received a composite bovine and Omniflow II synthetic graft. Of these 60 patients, 3 had required reconstruction surgery to treat a mycotic aneurysm, 25 because of early graft infection, and 24 to treat late graft infection. Finally, eight

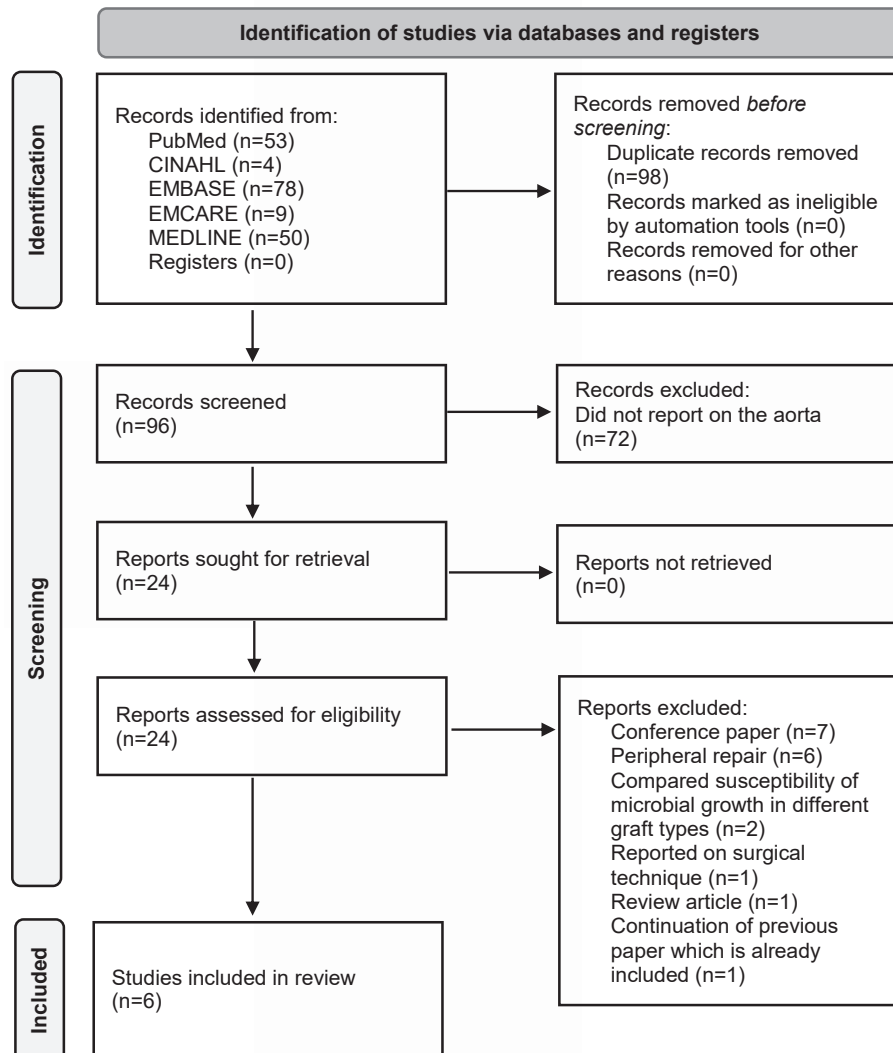


Fig 1. PRISMA (preferred reporting items for systematic review and meta-analysis) 2020 flow diagram outlining database search using inclusion criteria.

high-risk patients had received the Omniflow II graft to prevent graft infection (six had had stage IV peripheral arterial disease and two had required concomitant surgery for intestinal ischemia).

Aortofemoral repair was the most common site for repair (25 patients), followed by the abdominal aortoiliac artery (7 patients). The patient characteristics and repair location are presented in [Supplementary Table 1](#) (online only). All the studies had classified early graft infection as infection occurring <4 months after the index procedure and late graft infection as that developing >4 months after the index procedure. *Staphylococcus aureus*, *Escherichia coli*, and *S. epidermis* were the microorganisms isolated the most often from the infected grafts. For 7 patients, no microorganism was identified, and for 10 patients, the microorganism was not classified. The length of hospital stay ranged from 4 to 177 days and the operative time from 247 to 584 minutes.

The rate of mortality varied among the studies.⁹⁻¹¹ Keschenau et al⁹ reported an in-hospital mortality of 30% (6 patients) and late mortality of 10% (2 of 20 patients). In contrast, Betz et al¹¹ reported early mortality of 5.26% (1 of 19) and late mortality of 63.16% (12 of 19 patients). However, the follow-up duration in these studies had varied from a median of 3 to 6 months to 14 months.⁹⁻¹¹ el Beyrouti et al¹² reported late mortality for two patients, both of whom had been in the prevention group (ie, aortoiliac reconstruction using the Omniflow II graft for patients considered to have a substantial risk of subsequent graft infection). Of these two patients, one had died of respiratory failure secondary to bronchial carcinoma and one had died of multiorgan failure after undergoing multiple surgical interventions. Overall, early mortality had occurred in 8.83% of patients (95% confidence interval [CI], 1.12%-20.53%; [Supplementary Fig 1](#), online only; [Table](#)).

Table. Surgical outcomes and follow-up data

Investigator	Graft material for reconstruction	Early mortality, No.	Late mortality, No. ^a	Length of stay, days	Follow-up, months	Patency at follow-up, %	Freedom from reinfection, %
Betz et al, ¹¹ 2021 (n = 19)	Omniflow II for all	1	At 1 year after surgery, 5; at 3 years after surgery, 7	27 ± 15.9	3-6	100	94.7
el Beyrouti et al, ¹² 2021 (n = 16)	Omniflow II for all	1	2	Prevention group, 29.5; treatment group, 18.2	28.6 ± 17.2	100	93.75; prevention group, 88.9; treatment group, 100
Keschenau et al, ⁹ 2021 (n = 20)	Omniflow II, n = 8; bovine + Omniflow II, n = 12	In-hospital mortality, 7; sepsis, 4; bleeding, 1; mesenteric ischemia, 1; graft occlusion and ischemia, 1	Death during follow-up of nonaortic causes, 2	30 (4-177)	Estimated median follow-up, 14 (9-19)	95	100; Omniflow II, 100; bovine + Omniflow II, 100
Harmouche et al, ¹³ 2018 (n = 1)	Omniflow II	0	0	15	6	100	100
Krasznai et al, ¹⁰ 2016 (n = 3)	Omniflow II for all	0	Lung carcinoma 11 months postoperatively, 1	14 months (2-19 months)	24	100	66.7
Woźniak et al, ¹⁴ 2016 (n = 1)	Omniflow II + femoral vein	0	0	—	24	100	100

Data in parentheses are ranges.

The late mortality rate was 18.49% (95% CI, 5.51%-35.34%; Fig 2).

Early graft occlusion had occurred in 6.2% (95% CI, 0.39%-15.81%), and 3.83% (95% CI, 0.00%-16.34%) had developed early graft stenosis (Fig 3; Supplementary Fig 2, online only). The overall late graft occlusion rate was 0.01% (95% CI, 0.00%-4.61%; Supplementary Fig 3, online only). Only two cases of postoperative reinfection were reported. The freedom from reinfection rate for the patients treated with the Omniflow II graft only was 97.71% (95% CI, 87.94%-100.00%; Fig 4). The freedom from reinfection for the patients treated with a composite bovine and Omniflow II graft was 100% and was 88.9% for those treated preventatively with an Omniflow II graft.

The most common postoperative complications included pulmonary infection and sepsis (Supplementary Table II, online only). In most cases, the patients had had several complications. However, this could be expected from the magnitude of the surgery.

DISCUSSION

In the present systematic review, we identified a freedom from reinfection rate of 97.7% (95% CI, 87.94%-100.00%) with the use of the Omniflow II synthetic graft in the management of aortic infection. The early graft

occlusion rate was 6.2% (95% CI, 0.39%-15.81) and the early mortality rate was 8.83% (95% CI, 1.12%-20.53%).

Various considerations are key for determining the optimal type of graft material, including the risk of graft reinfection. Several studies have shown excellent outcomes with peripheral reconstruction using the Omniflow II graft for infected grafts, with no case of reinfection documented during follow-up.¹⁵⁻¹⁷ De Siqueira et al¹⁸ reported 100% freedom from reinfection after repair of vascular graft dehiscence at the femoral anastomosis using the Omniflow II graft.

A freedom from reinfection rate of 97.7% is similar to that reported by other studies. Hostalrich et al¹⁹ reported a 94% freedom from reinfection using a xenopericardial graft. Chakfé et al⁶ reported a higher reinfection rate of 11% after aortic reconstruction with silver-coated grafts. In addition, 100% freedom from reinfection after reconstruction with the bovine graft has been reported by Anibueze et al²⁰ in the management of mycotic and infected aortic grafts. However, their study had included only six patients.

Although the susceptibility to infection with the Omniflow II graft might appear comparable to that with the xenopericardial graft compared with the polytetrafluoroethylene graft, in a rat-based study, the Omniflow II graft was found to be more susceptible to infection.²¹ This

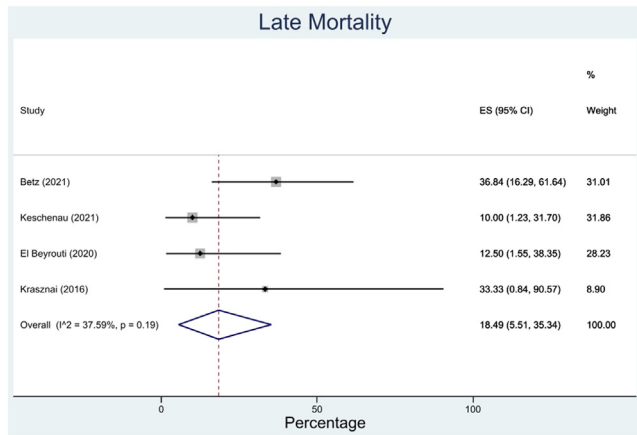


Fig 2. Pooled analysis of late mortality. *CI*, Confidence interval; *ES*, effect size.

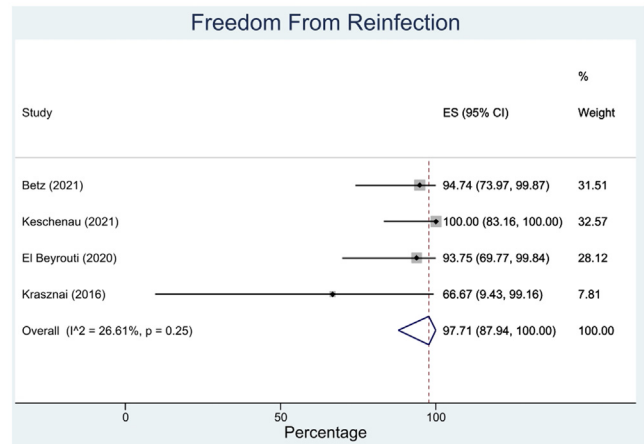


Fig 4. Pooled analysis of freedom from reinfection. *CI*, Confidence interval; *ES*, effect size.

finding has been further supported by in vitro studies in which the Omniflow II graft demonstrated greater susceptibility to bacterial colonization compared with bovine pericardial grafts and polytetrafluoroethylene grafts.² In a study by Koskas et al,²² 12 dogs had undergone thoracoabdominal aortic bypass using cadaveric human arteries or an expanded polytetrafluoroethylene graft and were then infected with *S. aureus* to develop bacteremia. In their study, none of the human grafts had grown bacteria and four of the six expanded polytetrafluoroethylene grafts had grown bacteria. However, these findings might not be representative of the reinfection rates for humans. In a meta-analysis, the polytetrafluoroethylene reinfection rate was 20%, which was significantly greater statistically than the reinfection rates observed with cryopreserved veins (9%), rifampicin-coated veins (11%), autogenous veins (6%), or silver-coated prostheses (11%) for infected aortic graft reconstruction.²³ The present pooled analysis of the Omniflow

II graft identified freedom from reinfection rates similar to those for autogenous veins.

In addition to the management of infected aortic grafts, the Omniflow II graft could be useful for reconstruction in patients considered to have a high risk of graft infection. el Beyrouti et al¹² explored this in a study in which the Omniflow II graft was used for aortic reconstruction in eight patients at risk of graft infection. They reported one reinfection in the prevention group (1 out of 9) and one graft occlusion in the treatment group (1 out of 7) (patients who had received the Omniflow II graft for aortic graft infection).

Although the data are conflicting, higher rates of infection with prosthetic grafts have been reported, likely resulting from the presence of foreign material. Although the Omniflow II graft has a polyester mesh, this is covered by ovine tissue; therefore, the truly prosthetic aspect remains covered. The Omniflow II graft cannot be soaked in rifampicin and, therefore, does not have any active antibacterial agent, an important quality for synthetic grafts. Although the Omniflow II graft performs well compared with xenopericardial grafts, the comparative evidence is insufficient to determine whether the performance of the Omniflow II graft will be superior or comparable to that of other graft materials (eg, polytetrafluoroethylene), although it does appear comparable to the findings reported in the general literature.

In addition to removal of the infected graft, debridement, and reconstruction, the perioperative and postoperative antibiotic regimen likely plays a key role in the morbidity and mortality. The approach to antibiotic therapy varied among the included studies. Betz et al¹¹ reported that anti-infective antibiotic therapy had been initiated intraoperatively and switched to oral administration after 2 weeks, which was continued for an additional 6 weeks. Keschenau et al⁹ reported individualized anti-infective therapy both peri- and postoperatively. The duration of antimicrobial therapy ranged from 2 to 6 weeks

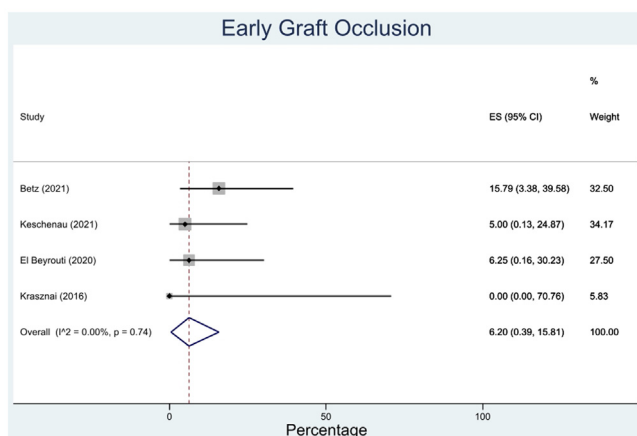


Fig 3. Pooled analysis of early graft occlusion. *CI*, Confidence interval; *ES*, effect size.

perioperatively. Further experimental analysis is required to determine the optimal duration of antimicrobial therapy and whether it should be tailored to each patient according to the microorganisms cultured.

The occlusion rate with the Omniflow II graft of 6.2% (95% CI, 0.39%-15.81%) in the present study appears comparable to that reported in a previous meta-analysis by Batt et al.²³ They reported a graft occlusion rate of 13%, 11%, and 10% for cryopreserved grafts, rifampicin-bonded prostheses, and polyester grafts, respectively (with no statistically significant differences). Kieffer et al²⁴ reported an aortic graft occlusion rate of 29.7% after infected infrarenal aortic graft reconstruction with cryopreserved grafts at 34 months. A high proportion of these cases were aortobifemoral grafts for occlusive disease, as would be expected with the Omniflow II graft, rather than tube grafts for aneurysmal disease; therefore, direct comparisons were not possible.

It was difficult to properly compare the graft occlusion risk with the Omniflow II graft. The occlusion rates of the aortic grafts differed between the studies, and the evidence was insufficient to determine whether the use of the Omniflow II graft represents superior or inferior graft material regarding the occlusion risk. Further data on the postoperative outcomes of aortic reconstruction with the Omniflow II graft, in particular, data on stenosis and occlusion, are required to determine whether the Omniflow II graft represents a viable option for graft material. In addition, the graft diameter and length were not reported, although the Omniflow II graft is available in diameters from 5 to 8 mm and lengths from 20 to 65 cm.

The risk of occlusion could result from preoperative complications independently of the graft used. In one of the studies by Betz et al,¹¹ all the patients had presented with severe sepsis and peripheral arterial disease with impaired outflow, which could have impaired coagulation and resulted in susceptibility to graft occlusion. Nonetheless, the poor outcomes with the presence of underlying sepsis could suggest reduced function for the Omniflow II graft in a coagulable environment and is an important consideration regarding the use of the Omniflow II graft. Investigation into the cause of mortality in these cases would assist in guiding decisions regarding whether the Omniflow II is appropriate graft material, especially for patients with severe sepsis, and whether higher blood pressure management or intravenous heparin infusion postoperatively would be appropriate to help maintain early graft patency.

In the present study, early mortality was 8.83% (95% CI, 1.12%-20.53%), and the late mortality was 18.49% (95% CI, 5.51%-35.34%). These rates are concerning but can be expected with this severity of pathology. The increased mortality was not always directly linked to the Omniflow II graft. Keschenau et al⁹ reported that of the deaths they observed during follow-up of Omniflow II patients, none

had been related to the aorta. Most deaths in their study had been secondary to sepsis with subsequent multiorgan failure.⁹ However, this finding is not unique to the Omniflow II graft. Sepsis with multiorgan failure was also the primary cause of death for 13 of 18 patients postoperatively who had been treated for aortic infection using xenogeneic reconstruction in a study by Hostalrich et al.¹⁹ In these studies, mortality was often linked to sepsis and did not necessarily depend on the type of graft used. Fundamentally, the mortality rates will vary between postoperative patients and will depend on key factors such as the patient's morbidity before surgery, urgency of repair, severity of disease, and microorganisms involved in infection.

Study limitations. The use of perioperative and postoperative antibiotic regimens is likely to play a key role in morbidity and mortality. The approach to antibiotic therapy varied in the included studies, which posed a challenge in analyzing and determining the ideal type and duration of perioperative antimicrobial therapy. Another fundamental limitation of the present review was the limited numbers of studies of the use of Omniflow II for aortic reconstruction and the small numbers of patients eligible for inclusion. Robust data are lacking to allow for statistical analysis of the results across studies to draw conclusions regarding whether the Omniflow II represents a viable graft material for aortic repair.

CONCLUSIONS

Although autologous grafts have been favored in vascular procedures, they will not always be a suitable choice for multiple reasons.⁶ First, in larger reconstructions such as those of the abdominal aorta, the choice of suitable autologous grafts will be limited, because the patients might not have veins suitable for use as a graft.¹¹ Second, vein harvesting can have a profound effect on survival and morbidity in urgent and emergent cases.^{15,25} In these cases, biosynthetic materials can provide a readily available option with reasonable outcomes.

As demonstrated in the present review, use of the Omniflow II graft as an aortic graft has been associated with favorable reinfection outcomes at several aortic levels. It is a reasonable choice for surgical management of both native and graft-related aortic infections and possibly represents a promising alternative to autologous grafts, especially in urgent and emergency cases. However, the number of studies remains limited and data are lacking, prohibiting a direct comparative analysis with the current treatment options. Further large cohort studies and *in vitro* data are required to determine whether the Omniflow II graft is truly a comparable treatment option to current graft materials and how reinfection risk could be reduced through the use of appropriate and possibly individualized antimicrobial regimens.

AUTHOR CONTRIBUTIONS

Conception and design: NE, PS

Analysis and interpretation: NE, AA, ZA, JB, PS

Data collection: NE, AW

Writing the article: NE

Critical revision of the article: NE, AW, AA, ZA, JB, PS

Final approval of the article: NE, AW, AA, ZA, JB, PS

Statistical analysis: Not applicable

Obtained funding: Not applicable

Overall responsibility: NE

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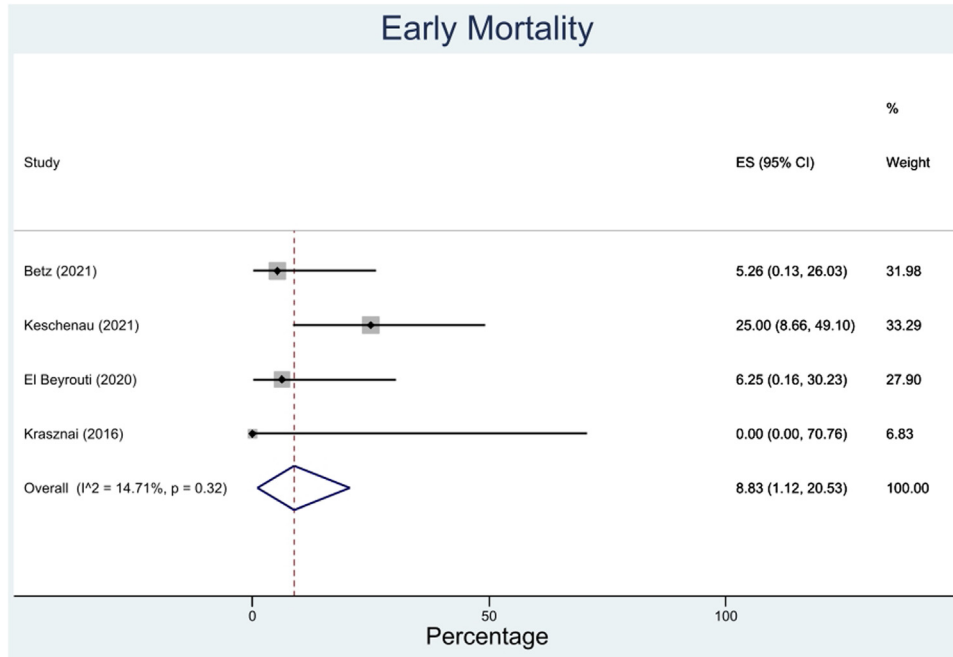
Supplementary Table I (online only). Summary of patient characteristics and surgical repair types

Investigator	Population, No. (male; female)	Surgical indication, ^a No.	Repair type, No.
Betz et al, ¹¹ 2022	19 (14; 5); median age, 66.6 years	Early graft infection, 6; late graft infection, 13	Aortobifemoral, 7; aorto-bi-iliac, 1; aortofemoral, 4; femoral interposition, 6; iliac–femoral, 1
el Beyrouti et al, ¹² 2021	16 (10; 6); mean age, 65.5 years; prevention group, 8; treatment group, 8	Prevention group, ^b 9 (1, mycotic aneurysm; 6, stage IV PAD; 2, concomitant intestinal ischemia surgery); treatment group, 2 early; 5, late	Aorto bifemoral, 12; aorto-bi-iliac, 4
Keschenau et al, ⁹ 2021	20 (16; 4); median age, 68.5 years (28-78 years)	Early graft infection, 16; late graft infection, 2; mycotic aneurysm, 2	Infrarenal, 9; juxtarenal, 6; thoracoabdominal, 3; arch, 2
Harmouche et al, ¹³ 2018	1 (male); 69 years	Late graft infection, 1	Infrarenal abdominal aorta
Krasznai et al, ¹¹ 2016	3 (2; 1); median age, 66 years (64-67 years)	Late graft infection, 3	Aortobifemoral, 1; aortoiliac, 2
Woźniak et al, ¹⁴ 2016	1 (male); 73 years	Early graft infection	Aortobifemoral

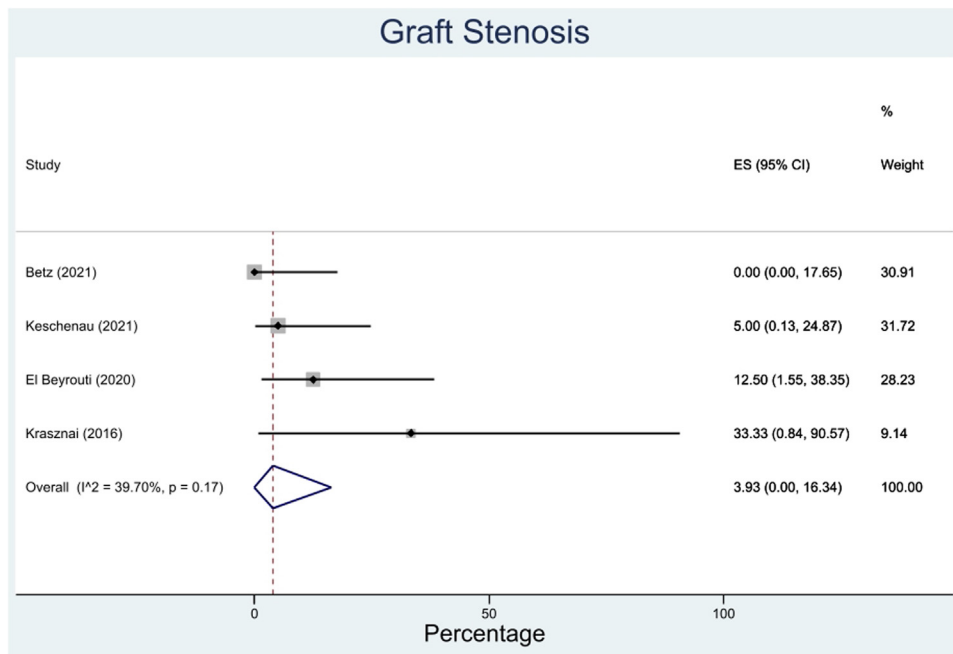
PAD, Peripheral arterial disease.
^aEarly graft infection defined as <4 months after index procedure, late infection is defined as >4 months after index procedure.
^bEarly and late could not be applied because the prevention group had undergone reconstruction with the Omniflow II graft to prevent an initial graft infection.

Supplementary Table II (online only). Early and late complications after reconstruction with Omniflow II synthetic graft and composite bovine and Omniflow II synthetic graft

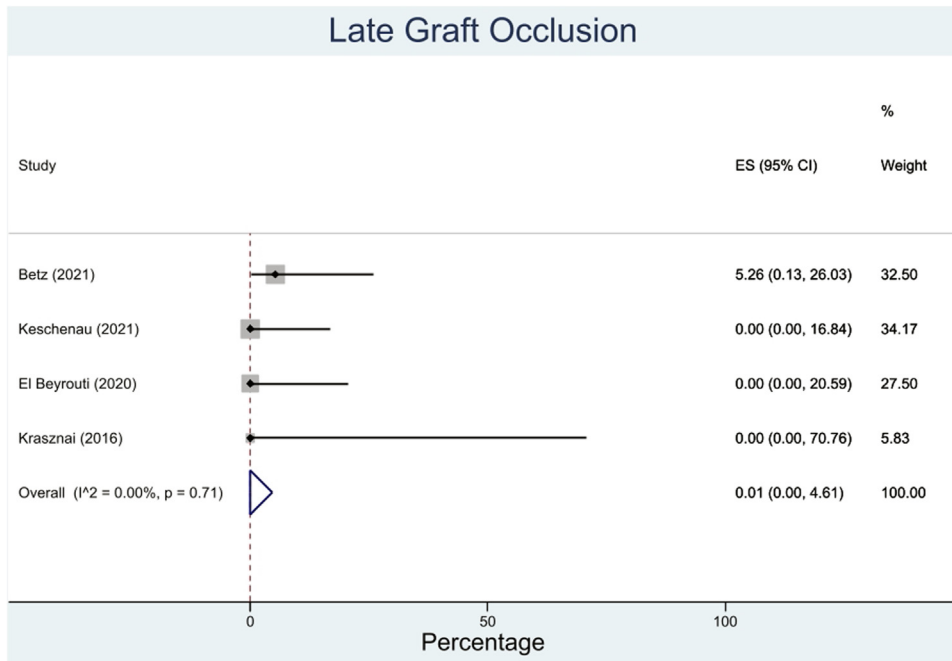
Variable	Omniflow II group (n = 56)	Composite bovine pericardial tube graft with Omniflow II extension (n = 15)
Early complication, No.		
Amputation	1	–
Bowel perforation	1	–
Compartment syndrome	–	1
Congestive heart failure	1	–
Death with dialysis	2	2
Deep vein thrombosis	1	–
Extremity ischemia	–	1
Gluteal ischemia	–	1
Graft occlusion	5	–
Graft stenosis	2	–
Hematoma or sarcoma	4	–
Intestinal ischemia	1	–
Major bleeding	2	1
Malignant hypertension	–	1
Mesenteric ischemia	–	1
Minor subarachnoid bleeding	1	–
Multiorgan failure	–	2
Myocardial infarction	1	1
Prolonged/paralytic bowel ileus	1	2
Pulmonary infection	5	6
Renal failure	–	2
Respiratory insufficiency due to pneumonia	1	–
Sepsis	1	5
Tracheostoma	2	–
Transient dialysis	–	3
Transient liver failure	–	1
Wound infection	2	–
Late complication, No.		
<i>Campylobacter jejuni</i> infection	1	–
Fluid collection	1	–
Graft occlusion	7	–
Graft reinfection	3	–
Graft stenosis at anastomosis	–	1
Incisional hernia repair	–	1
Ischemic stroke	1	–
Major amputation	3	–
Myocardial infarction	1	–
Stenosis of allograft	1	–
Ureteroiliac fistula	1	–
Urinary infection with <i>Enterococcus faecium</i>	1	–



Supplementary Fig 1 (online only). Pooled analysis of early mortality. *CI*, Confidence interval; *ES*, effect size.



Supplementary Fig 2 (online only). Pooled analysis of early graft stenosis. *CI*, Confidence interval; *ES*, effect size.



Supplementary Fig 3 (online only). Pooled analysis of late graft occlusion. *CI*, Confidence interval; *ES*, effect size.