Treatment of Aorto-iliac and Infrainguinal Vascular Infections with a Prefabricated Bovine Pericardial Graft

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Background: The use of biological grafts provides acceptable mid- and long-term results in native or prosthetic vascular infections. Several reports describe the successful use of bovine pericardium in case of vascular infections, mainly as a large patch to be sutured as a tubular graft. Recently, a novel prefabricated bovine pericardium graft (Biointegral Surgical No-React® Inc, Mississauga, ON, Canada) has been introduced in clinical practice with promising results. In this study, we report our preliminary experience utilizing Biointegral Surgical graft in case of native and or prosthetic aorto-iliac and infrainguinal infection.

Methods: We retrospectively analyzed data from 20 patients with native or prosthetic aorto-iliac and infrainguinal infection who underwent in situ reconstruction (ISR) with a Biointegral Surgical No-React bovine pericardium prosthesis between October 2020 and February 2023 at the Vascular Surgery Unit of the Fondazione Policlinico Universitario Gemelli − IRCCS in Rome, Italy.

All patients followed a standardized protocol including postoperative anticoagulation and long-term intravenous antibiotics.

Results: The indication for surgery was: mycotic aortic aneurysm in 4 patients (20%), graft infection after abdominal aortic repair in 11 patients (55%), peripheral graft infection in 5 patients (25%). Complete excision of the infected aorta or prosthetic graft, surgical debridement and ISR were performed in all patients. Hospital mortality rate was 5% ($n = 1$) and graft-related mortality of 0%. During follow-up (median 13 months, range 6−34 months), reinfection was 5.2% and primary graft patency 94.7%.

Conclusions: The use of prefabricated bovine pericardial grafts represents a promising option for the treatment of native and prosthetic aorto-iliac and infrainguinal infections. The application of this biological graft with a standardized postoperative protocol has been associated with a satisfactory patency and reinfection rate without increased bleeding complications.

Authorship notes: Federica Donato and Tommaso Donati contributed equally to the manuscript.

Conflict of interest: None.

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Ann Vasc Surg 2024; 105: 177–188
https://doi.org/10.1016/j.avsg.2024.01.015

Manuscript received: September 24, 2023; manuscript accepted: January 1, 2024; published online: 9 April 2024

INTRODUCTION

Infection of native arteries or prosthetic vascular grafts is a rare but potentially devastating complication in vascular surgery, with a reported incidence of 0.7%−2.6%[1] of infected abdominal aortic aneurysms, 0.2−3% of prosthetic graft infection and 1−1.2% of endovascular device infections.[2] They still represent a major challenge in vascular surgery, with high morbidity and mortality rates (up to 30%)[3] and high major amputation rates (12%−70%)[4] even after replacement of the infected graft. Open surgery, with excision of the infected aorta or prosthetic graft and local debridement followed by aortic reconstruction, is widely considered the best option for definitive eradication of the infection in both native and aortic graft infection.[2,5]

Among various possible interventions, in situ reconstruction (ISR) seems to have the best long-term results, offering a safe and effective alternative to extra-anatomic reconstruction,[6,7] which is feasible but with a risk of graft failure and a high rate of infection.[8]

The choice of the ideal material for vascular reconstruction is still debated.[5−7,9]

Autologous material such as saphenous and femoral veins seem to be the preferred option, as recently emphasized in the European Society of Vascular Surgery's 2020 guidelines on the management of vascular endograft infections.[10] Disadvantages include harvesting difficulties and prolonged surgery in the emergency setting, size and length mismatch and secondary dilatation. Alternatively, preserved allografts showed low rates of reinfection (0%−7%),[10] while silver-coated and rifampicin-impregnated grafts are readily available but are burdened with a significantly higher risk of reinfection (11%).[10−13]

Bovine pericardium is a well-known material available for aorto-iliac and femoral infections, mainly as a large patch to be sutured as a tube graft based on the specific anatomy to be treated and reports to date on its resistance to reinfection are promising.[5−7,14]

BioIntegral Surgical No-React® Vascular Grafts (BioIntegral Surgical Inc, Mississauga, Ontario, Canada) is a prefabricated bovine pericardium graft that has recently become commercially available.

This preliminary experience aims to analyze early outcomes of our first experiences with BioIntegral Surgical No-React® (BioIntegral Surgical Inc, Mississauga, ON, Canada) bovine pericardial prosthesis for native or prosthetic aorto-iliac and infrainguinal graft infection.

METHODS

In this retrospective cohort study, we analyzed prospectively collected data of 20 patients with native or prosthetic aorto-iliac and infrainguinal infection who underwent ISR with a BioIntegral Surgical No-React® (BioIntegral Surgical Inc, Mississauga, ON, Canada) bovine pericardial prosthesis, between October 2020 and February 2023 at the Unit of Vascular Surgery of Fondazione Policlinico Universitario Gemelli − IRCCS in Rome, Italy.

This study was approved by the Local Ethics Committee and informed consent was obtained from the included patients. The study is registered on ClinicalTrials.gov with the identification code NCT05777681.

Diagnosis

Diagnosis of aorto-iliac and infrainguinal infection was based on clinical/surgical, radiologic and microbiological findings (in case of graft infection, as suggested by the ''Management of Aortic Graft Infection Collaboration'', MAGIC).[15]

In case of native infection, the diagnosis was based on a combination of clinical presentation, laboratory results and corroborative imaging findings on computed tomography (CT), according a recent literature.[16]

Fluorine-18-fluorodeoxyglucose positron emission tomography-computed tomography (PET/CT) was a useful additional tool for the evaluation of graft and native infections in hemodynamically stable patients, particularly when the diagnosis of infection was uncertain.

Multiple samples of perivascular tissue and removed graft material were collected in all patients and sent for microbiological examination. Patients were observed with regular postoperative follow-up, which included clinical examination, blood and radiological tests including CT after 1, 3 and 12 months and PET/TC after 6, 18, 24 months.

All cases were always discussed in a multidisciplinary team (vascular team), including vascular surgeons, internal medicine and infectious disease specialists, in order to define the best diagnostic and therapeutic strategy for each individual patient.

End Points

30-day primary end points were graft reinfection, graft occlusion, anastomotic dehiscence or aortic bleeding and in-hospital mortality. Early end points included overall mortality, graft reinfection, graft occlusion or dilatation, late reintervention (defined

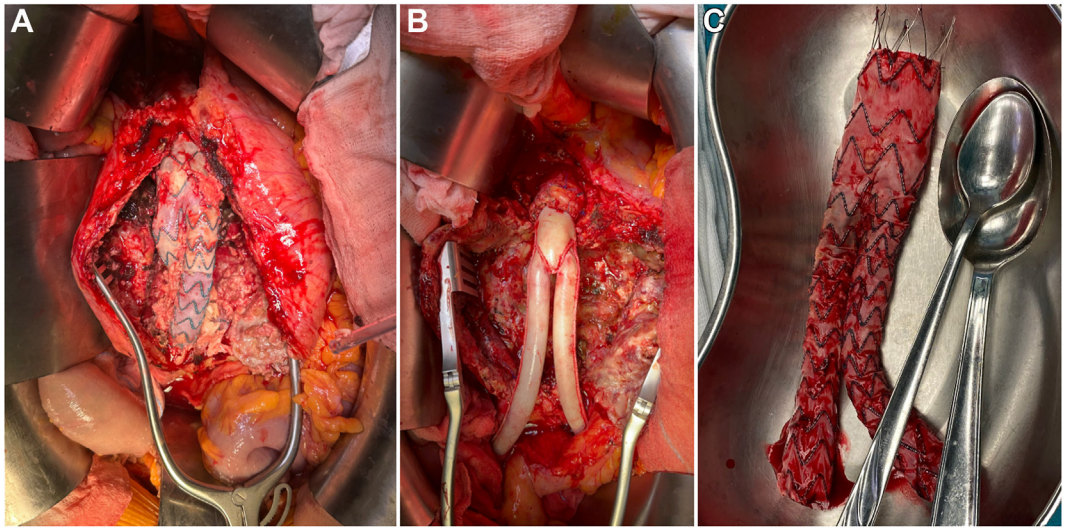

Fig. 1. (A) Infected graft before explantation. **(B)** In situ reconstruction with Biointegral Surgical No-React® bovine pericardial bifurcated graft. **(C)** Complete explantation of infected graft.

as graft-related or laparotomy 1 month after the index surgery).

Surgical Technique

Once the diagnosis was made, patients underwent expedite surgery with excision of the infected aorta or prosthetic graft, surgical debridement and ISR. (Fig. 1).

Aortic access was mainly performed through a retroperitoneal approach or thoracophrenolaparotomy. In cases of peripheral infections, surgical access was performed through a retroperitoneal or femoral approach. Aortic anastomosis was performed end-to-end or side-to-end with nonabsorbable monofilament sutures.

According to the instructions for use, Teflon strips or pledgets, glutaraldehyde-based hemostats and sutures 2-0 or bigger were not used.

BioIntegral Surgical No-React Vascular Grafts

BioIntegral Surgical No-React Vascular Grafts (BioIntegral Surgical Inc, Mississauga, Ontario, Canada) is a prefabricated bovine pericardial graft cross-linked with glutaraldehyde and detoxified using a unique No-React® process.

Bovine pericardium is cleaned and rinsed, cross-linked with glutaraldehyde solutions, and then the tissue is stripped of pericardium, laminated, and closed with 3 layers of manual suture.

Finally, the graft undergoes the ''No-React'' procedure: it is freed from aldehyde residues by repeated rinses with saline and heparin. The No-React® process makes the graft biocompatible, anti-infective and prevents blood clotting, also promoting the establishment of endothelial cells on the surface in contact with the blood.[17,18]

Antibiotic and Medical Therapy

The type and duration of antimicrobial therapy were based on the recommendations of infectious disease specialists. All patients initially received empirical broad-spectrum intravenous antimicrobial therapy, which was then modified based on the results of blood cultures and/or intraoperative microbiological cultures. In some cases, patients who were prescribed prolonged intravenous therapy at discharge continued antibiotics through an outpatient parenteral antimicrobial therapy service (at home or in the Infectious Disease Ambulatory).

Patients with aorto-enteric fistula (AEF) received additional antifungal treatment, starting immediately after surgery. The regimen and duration of postoperative antimicrobial therapy depended on the type of pathogen, intraoperative findings and clinical course, but a minimum treatment period of at least 3 months with at least 6 weeks of endovenous antimicrobial therapy was always achieved.

According to the instructions of manufacturers for use of the Biointegral Surgical graft protocol, all patients received anticoagulant therapy for at least 6 weeks after surgery with anticoagulant doses

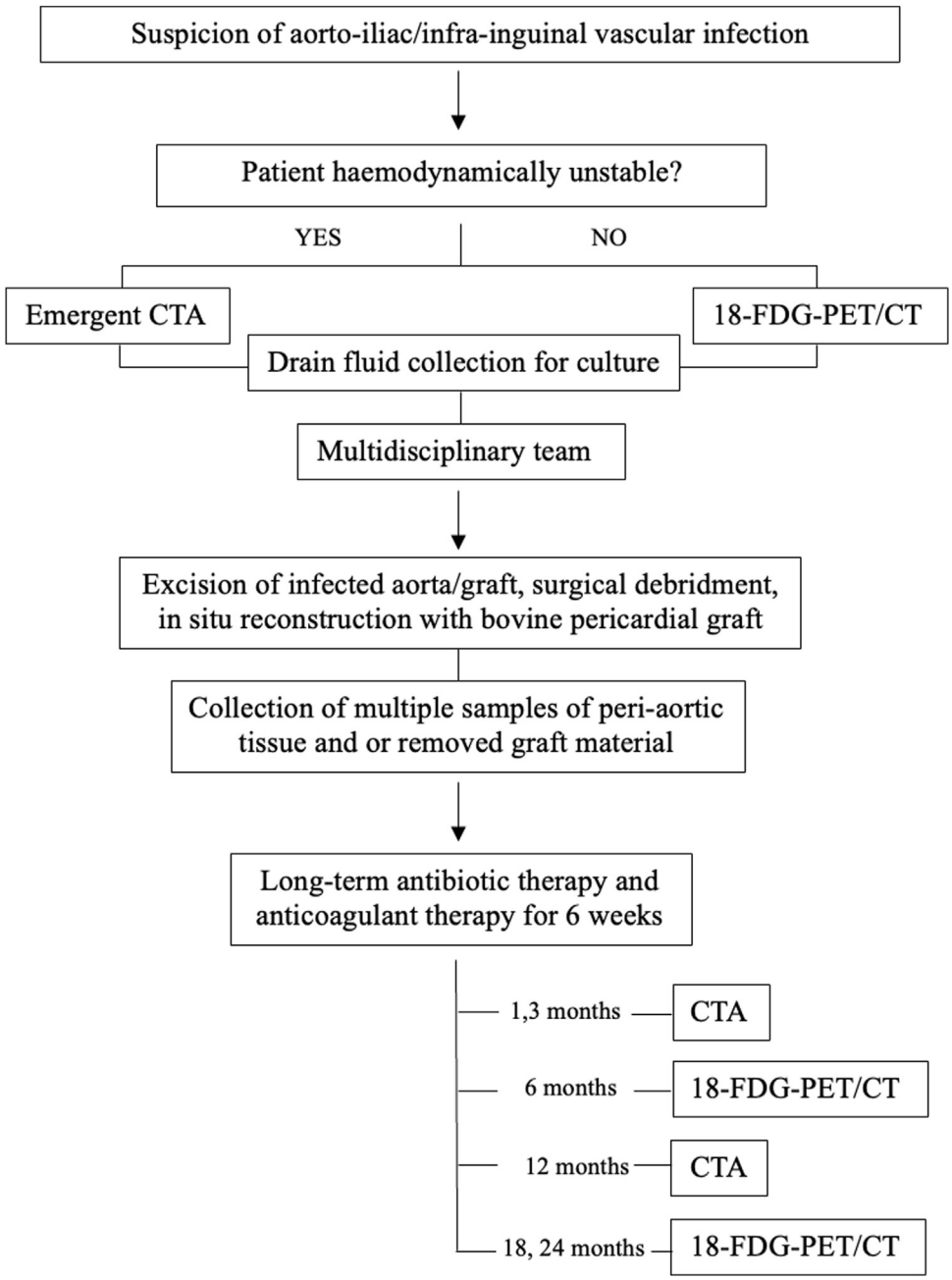

Fig. 2. Proposed algorithm for the management of native or prosthetic aortic infections.

of low-molecular- weight heparin (LMWH). In addition, each patient received single antiplatelet therapy.

A structured clinical approach helps clinical decision making and aims to improve the clinical outcome of patients.[19]

Proposed algorithm for the management of native or prosthetic aortic infections is reported in Figure 2.

RESULTS

Between October 2020 and February 2023, a total of 20 patients (17 men and 3 women) with a median age of 70.5 years (range 38–87 years) were treated with BioIntegral Surgical No-React® bovine pericardial prosthesis for vascular reconstruction.

Patient's demographics and comorbidities are summarized in Table I.

Table I. Patient's demographics and comorbidities

Patients	No. = 20	%
Median age	70,5	range 38–87
Male gender	17	85
Comorbidities		
Smoking	10	50
Hypertension	13	65
Dyslipidemia	11	55
Diabetes mellitus	6	30
History of cardiovascular disease	9	45
Chronic obstructive pulmonary disease	4	20
Chronic kidney disease	6	30
Cancer	4	20
ASA classification		
ASA I	1	5
ASA II	3	15
ASA III	13	65
ASA IV	3	15

The indication for surgery was: mycotic aneurysm in 4 patients (20%), graft infection after abdominal aortic repair in 11 patients (55%) and peripheral graft infection in 5 patients (25%). Of the 16 patients with graft infection, 7 (43.7%) had previously undergone endovascular repair, 3 (18.7%) open aortic repairs, 5 (31.2%) surgical peripheral bypass and 5 (31.2%) ilio-femoral stenting, with 4 patients undergoing more than one type of treatment.

Clinical presentations varied among patients: abdominal pain and fever were the most common features (17 of 20 patients, 85%, reported at least one of the 2). Two patients also complained of progressive weight loss in the previous months. Importantly, 6 patients had clinical signs of sepsis (tachypnea and hemodynamic instability) at the time of diagnosis.

Seven patients (35%) had a contained rupture of the aneurysm at CT angiography with stable hemodynamic conditions. Patients with peripheric infection presented a cutaneous fistula in most cases (66.6%, 4 of 6 patients). Importantly, 4 of 20 patients (20%) had an aortic-enteric fistula. Patients' clinical presentation are shown in Table II.

All patients underwent surgical debridement and ISR.

In case of prosthetic graft infection, total explantation of the infected prosthesis was performed. Emergency surgery (within 24 hours) was performed in most patients (80%). For reconstruction,

Table II. Patient's clinical presentation

Symptoms	No = 20	%
Fever	12	60
Abdominal pain	6	30
Contained/free rupture	7	35
Cutaneous fistula	4	20
Aorto-enteric fistula	4	20
Sepsis	6	30

9 bifurcated grafts and 11 straight grafts were implanted in situ. Suprarenal clamping was required in 7 patients; clamping at the level of the descending thoracic aorta was necessary in 2 cases. Four patients required concomitant digestive surgery due to AEFs: duodenal suture in 3 patients, jejunal resection in 1 patient.

Intraoperative bacteriological samples were obtained in all patients.

Details of clinical data and microbiological results are shown in Table III.

The median length of hospital stay was 13.5 days (range 1–36 days) with an in-hospital mortality rate of 5% ($n = 1$).

No graft reinfection, graft occlusion, anastomotic dehiscence or aortic bleeding occurred at 30 days.

During follow-up (median 13 months, range 6–34 months), we documented 2 additional deaths: one from septic shock due to a lumbar spondylodiscitis unresponsive to antimicrobial therapy in a patient not eligible for orthopedic surgery; the others due to massive pulmonary embolism and cardiovascular collapse. No patients were lost to follow-up.

Graft-Related Mortality Was 0%.

Reinfection was documented in one of 19 patients survived at 30- postoperative day (5.2%).

Complete resolution of infection resulted in normalization of clinical conditions and improvement in radiologic findings (Fig. 3).

Reinfection occurred in a patient in whom, despite control of the primary infection, reinfection of the graft by enteric organisms developed. The patient had already undergone partial explantation of the infected endoprosthesis with aortic replacement using a silver-coated graft. After 3 months, due to graft reinfection, he underwent a complete graft explantation and ISR with a BioIntegral Surgical No-React®, with intraoperative evidence of aortic-enteric fistula, which was repaired. Six months later, we documented kinking and consequently bilateral branch thrombosis, requiring extra-anatomic revascularization, followed by initiation of antifungal therapy due to positive thrombus

Table III. Detailed information on the perioperative results after implantation

Pt	Site of infecti on	Fistula	Type of recon-structio n	Suprare nal clampin g	Operati on time (min)	Blood transfusi on (n° GRC)	Intra/Peri-Operative complicati ons	Organism
1	Aorto-bi-iliac graft	Aorto-jejunal	Bifurcat ed	None	340	1	None	*MRSA, E.coli; K. pneumonia, A. odontoliticus; C. albicans*
2	EVAR	None	Bifurcat ed	Yes	363	8	None	*S. Aureus methicillin-susceptible*
3	EVAR	Aorto-duoden al	Bifurcat ed	None	410	6	None	*S. constellatus, A. odontoliticus, E.coli, E. faecalis, C. albicans*
4	Ilio- femora l graft + femora l stent	Cutane ous	Tube	None	238	0	None	*C. Striatum*
5	Iliac stent + femora l patch	None	Tube	None	168	0	None	*E. coli*
6	EVAR	None	Bifurcat ed	Yes	325	3	None	*S. Aureus methicillin-susceptible*
7	Iliac stent	None	Bifurcat ed	None	390	4	None	*Salmonella*
8	Mycoti c aneury sm	None	Tube	None	192	0	None	*Salmonella*
9	Ilio- femora l graft	Cutane ous	Tube	None	360	0	None	*S. Marcescens*
10	Mycoti c aneury sm	None	Tube	Yes	340	2	None	*S. Aureus methicillin-susceptible*
11	Ilio- femora l graft	Cutane ous	Tube	None	160	0	None	*S. agalactiae, E. coli, B. fragilis, F. magna*
12	EVAR	None	Bifurcat ed	Yes	338	1	None	*E.coli*
13	EVAR + iliac branch	Aorto-duoden al	Bifurcat ed	None	418	6	None	*E. cloacae, B.tetaiotaomic ron, S. epidermidis, C. krusei*
14	Aorto-femora l graft	Aorto-duoden al and aorto-duoden al	Tube	Yes	490	5	None	*S. Anginosus, A. odontoliticus, P.micra*
15	Femor o- poplite al graft	Cutane ous	Tube	None	360	3	None	*E. fecalis, C. Simulans*
16	EVAR + renal chimne y	None	Bifurcat ed	None	300	3	None	*B. Nordii*
17	Aorto-iliac graft + axillo-femora l graft	None	Bifurcat ed	Yes	498	3	None	*E. coli*
18	Mycoti c aneury sm	None	Tube	Yes	283	3	None	*S. Aureus methicillin-susceptible*
19	Mycoti c aneury sm	None	Tube	None	98	0	None	*M. Tubercolosis*
20	EVAR + iliac stent	None	Tube	None	447	2	None	*E. Granulosus*

EVAR, EndoVascular Aneurysm Repair.

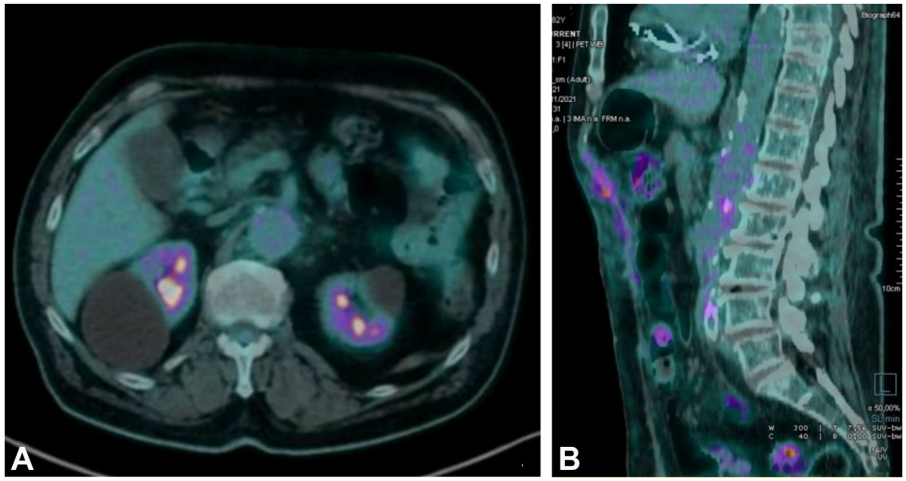

Fig. 3. (A and B) Diminution of positive glucose uptake at PET/TC suggestive of improvement of infection.

culture of Candida albicans and serum beta-d-glucan positivity. The patient received chronic antimicrobial suppressive therapy and is still alive 28 months after the last surgery.

Primary graft patency was 94.7% (18 of 19 patients survived at 30-postoperative day).

During follow-up, 2 patients developed an anastomotic pseudoaneurysm. One patient developed a pseudoaneurysm of the reimplanted renal artery after 2 months and underwent endovascular exclusion of the pseudoaneurysm with endograft.

Endovascular repair seemed to us to be a feasible alternative to simple observation or conventional surgery in a patient unfit for repeat open surgery, as supported by literature data.[20]

The patient achieved clinical stability and patency of the new graft after 24 months since the last procedure (Fig. 4).

An additionally small pseudoaneurysm involving the proximal and distal graft anastomoses was documented in a patient who underwent aortoiliac bypass 8 months after surgery. The patient underwent conservative treatment and strict follow-up.

Detailed analysis of patient follow-up data is showed in Table IV.

All outcome parameters are summarized in Table V.

DISCUSSION

Bovine pericardium is an increasingly used material in recent years for aortic infections, with promising results in terms of low rates of reinfection and graft failure.[5,6,14,21–24]

Compared with autologous vein grafts, it has the advantage of overcoming the size mismatch that can be the main limiting factor for this type of graft, causing aortic stenosis or limiting usability in several aortic segments.[21] No additional tissue incision is required, reducing operative time and an advantage in emergency situations.

Bovine pericardium appears to show a lower probability of calcification than allograft[8] and has greater availability, considering that the process of harvesting and preserving grafts is complex and not available in every hospital.

A significant advantage of Biointegral Surgical No-React bovine pericardium prosthesis is that it is prefabricated and available off-the-shelf, without the need for additional preparation and suturing time to create bifurcated or tubular grafts using bovine patches.

Due to the lack of consensus about the clinical role of biologic grafts, clinical series and observational cohort studies are crucial. Based on the results of the recent literature, complete explantation of aortic grafts with in situ biological reconstruction could represent a first-line management for aortic graft infections,[25] as shown by an overall mid-term survival rate of 73% and 67% of surviving patients with complete resolution of infection documented in a recent report of 54 patients with aortic graft infection underwent removal of infected material and biological neoaortic reconstruction.[25]

These results suggest significant improvements in the therapeutic approach to patients with vascular infections. A multidisciplinary approach, a structured diagnostic algorithm and aggressive surgery with complete removal and replacement with a

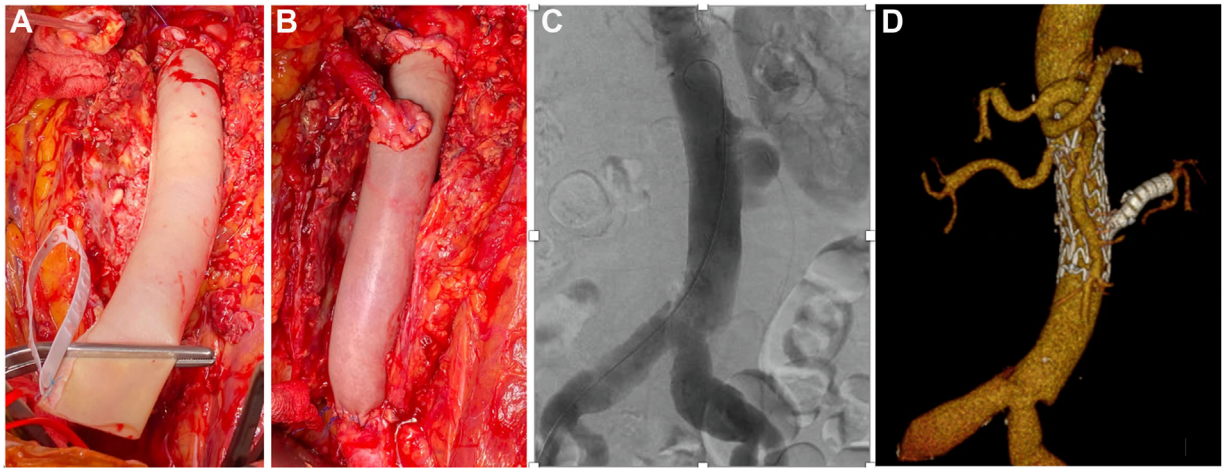

Fig. 4. (A and B) Reconstruction with Biointegral Surgical No-React® bovine pericardial tubular graft with reimplantation of renal artery. **(C)** Evidence of renal artery reimplanted pseudoaneurysm. **(D)** Endovascular exclusion of the pseudoaneurysm with endograft of the pseudoaneurysm with endograft.

biological prosthesis could radically change the prognosis of these patients.

Although other clinical series using the biological graft of our study have been published,[17,18,26] the association of the use of this graft with postoperative anticoagulant therapy and long-term antibiotic therapy has not been reported[17] or not well defined.[18,26]

We reported satisfactory results, even compared to previous series (reinfection rate 5.2% vs. 11%,[17] primary patency rate 94.7% vs. 86%[17]), although with a different follow-up period (median 13 months vs. 21.6 months[17]).

Our results are also in line with a recent prospective multicenter study that included a cohort of 34 patients, with promising results in terms of reinfection, mortality and graft occlusion.[24]

Antibiotic and anticoagulation therapy for 6 weeks after graft implantation is strongly recommended by manufacturers.

Thrombotic factors, such as fibrin, are produced by damaged blood vessels. Fibrin not only initiates the coagulation cascade, resulting in platelet aggregation, but is also closely related to initiation of infection, as biofilm formation requires the conversion of fibrinogen to fibrin.[27]

Biofilms contain receptor binding sites for bacteria that allow the formation of bacterial colonies that can lead to local and blood stream infections.[27,28] Preventing fibrin deposits, anticoagulants thereby reducing not only thrombosis but also the risk of reinfection. It occurs in particular areas of the surrounding tissue, such as the suture area.

Within 6 months after implantation, due to their high biocompatibility, the blood-contact surfaces of biological devices become covered with a single-cell layer of endothelial cells that is able to significantly reduce the risk of reinfection by acting as a natural anticoagulant and as a surface that literally captures and digests bacteria.[29,30]

However, as long until the surface of the device is completely covered by endothelial cells, the tissue is still vulnerable to bacterial exposure. This occurs in about 6 weeks, which is the recommended duration for anticoagulant treatment.

Anticoagulants, therefore, could act not only to reduce the thrombotic risk, but would be essential as protection against infection during endothelialisation of the graft.

We chose to use LMWH at anticoagulant doses without switching to oral anticoagulants due to possible interactions between anticoagulant and antibiotic therapy, particularly the risk of bleeding[31,32] and considering the short duration of anticoagulation treatment needed.

While in patients with peripheral arterial disease, data from the COMPASS trial[33] already suggest that low-dose anticoagulant plus aspirin is the preferred treatment strategy, no data are available on patients with infections. There are also no data available in the literature about the use of anticoagulant in aortic disease. However, in our cohort of patients the use of postoperative anticoagulant has not been associated with major bleeding.

The routinely administration of postoperative anticoagulant and long-term antibiotic therapy reduced graft complication and minimized graft reinfection. The only reinfection occurred in a

Table IV. Detailed analysis of patient follow-up data

Pt.	Follow- up (months)	Complication during follow-up	Aortic Reinterventions	Graft patency at the end of follow-up	Freedom from graft reinfection
1	34	Kinking and consequently thrombosis of bilateral branch Reinfection	Axillo-bifemoral bypass	Occluded	No: reinfection
2	33	None	None	Patent	Yes
3	4	Death from septic shock due to persistent retroperitoneal infection and refractory spondylodiscitis	None	Patent	Yes
4	29	None	None	Patent	Yes
5	28	None	None	Patent	Yes
6	26	Pseudoaneurysm of the renal artery implanted	Endovascular exclusion of the pseudoaneurysm	Patent	Yes
7	25	None	None	Patent	Yes
8	22	None	None	Patent	Yes
9	18	None	None	Patent	Yes
10	1,5	Death due to massive pulmonary embolism	None	Patent	Yes
11	16	None	None	Patent	Yes
12	14	None	None	Patent	Yes
13	12	Perianastomotic pseudoaneurysms	None	Patent	Yes
14	12	None	None	Patent	Yes
15	-	Death in the first postoperative day due to cardiovascular collapse	None	-	-
16	7	None	None	Patent	Yes
17	7	None	None	Patent	Yes
18	6	None	None	Patent	Yes
19	7	None	None	Patent	Yes
20	6	None	None	Patent	Yes

patient with severe polymicrobial and fungal infection with an AEF. No anastomotic dehiscence or aortic bleeding has been reported.

We documented only one graft occlusion, which occurred in a patient with kinking and subsequent bilateral branch thrombosis. This prosthesis has 2 continuous and one interrupted suture lines that ensure leak tightness and, as a result of these 3 suture lines, the side stitching is relatively rigid and kinking can occur. Based on our experience, we believe that it is crucial to tension the prosthesis stitching to prevent kinking, especially in bifurcated grafts.

In our opinion the development of anastomotic pseudoaneurysms in 2 patients is related to the fragility of the native aortic tissue, weakened by systemic infection.

Vascular infections still have high morbidity and mortality rates (up to 30%),[3] with mortality remaining high even after radical surgery (10–20%).[34]

Considering the severity of the initial disease, the resulting morbidity and mortality rate in our study seemed acceptable and we reported satisfactory results compared to previous series (30-day mortality of 5% vs. 9.5%,[17] overall mortality of 15% vs. 25%,[17] although clearly limitations of the different follow-up period. In fact, it is obvious that the longer the follow-up period, the more events are likely to occur.

The only death in the 30-day period was no aortic or graft-related and it occurred in the patient with severe aortic stenosis not eligible for conventional cardiac surgery and awaiting transcatheter aortic valve implantation (TAVI). The patient died in the first postoperative day, due to cardiac arrest.

The other deaths during the follow-up occurred in one patient with deteriorating clinical condition due to massive paraneoplastic pulmonary embolism and in another patient with an AEF and a lumbar spondylodiscitis unresponsive to antimicrobial therapy, due to septic shock.

Table V. Outcome characteristics

Freedom from graft reinfection	94.7
Freedom from aortic reintervention	84.2
Graft occlusion	
Early	-
Late	5.2
Anastomotic pseudoaneurysm	10.5
Anastomotic dehiscence	
Anastomotic bleeding	-
Mortality	
In-hospital mortality	5
Mortality after discharge	10
Overall mortality	15

Data are presented as *n* (%).

On note, despite the short follow-up period, we found no problems related to graft durability, such as in cases of disintegration of the Shelhigh No-React graft used in cardiac surgery.[35–37]

At the end of the 1990s, a new prefabricated biological conduit (Shelhigh®, Inc., Millburn, NJ, USA) consisting of a bovine pericardial straight graft with an incorporated porcine stentless valve, was introduced in Europe from the same company for use in cardiac surgery.[38,39] Despite satisfactory short-term results, long-term follow-up revealed a relatively high rate of deaths and reinterventions, with some dramatic cases of patients presenting with sudden disintegration of the graft.[35–37]

Although significant concerns regarding a suspected contamination of BioIntegral bioprosthetic heart valves with Mycobacterium chelonae,[40] which led the company to the temporary hold on all implantations and sales of the products, growth studies were performed in 4 labs, and no positive cultures were found. The company no longer recommends a hold on any of its products and they remain in conformity. Currently, after the initial field safety notice, hold has been lifted in the United Kingdom and countries outside the European Economic Area.

Vascular infections represent one of the main challenges in vascular surgery and clinical discussion in a multidisciplinary team including vascular surgeons, internal medicine physicians and infectious disease specialists is essential in order to define the best therapeutic strategy for each individual patient. It may also be useful to use a flow chart, which can help identify the essential steps in the diagnostic and therapeutic process and, at the same time, provide an overview of the process. The severity of disease imposes the need for long-term surveillance and strict follow-up with CT and PET/CT.[41,42]

Study Limitation

Our study clearly has limitations. The small sample analyzed, the heterogeneity of the sample analyzed, the short follow-up time, and the lack of comparison with other materials, hampers definite conclusions.

CONCLUSIONS

Pending results from longer follow-up and increasing clinical experience, it should be highlighted that in our case series, the use of prefabricated bovine pericardial graft with associated administration of anticoagulant and long-term antibiotic therapy has shown satisfactory 30-day outcomes, with high patency rates and a low reinfection rate, prompting the need for longer follow-up, longitudinal studies.

CREDIT AUTHORSHIP CONTRIBUTION STATEMENT

Federica Donato: Writing – review & editing, Writing – original draft, Visualization, Software, Resources, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Tommaso Donati:** Writing – review & editing, Visualization, Validation, Supervision, Project administration, Conceptualization. **Fabrizio Minelli:** Visualization, Validation, Data curation, Conceptualization. **Alberto Borghetti:** Visualization, Supervision, Data curation, Conceptualization. **Marta Minucci:** Visualization, Data curation, Conceptualization. **Antonio Luparelli:** Visualization, Resources, Data curation. **Giovanni Tinelli:** Writing – review & editing, Validation, Supervision, Conceptualization. **Yamume Tshomba:** Writing – review & editing, Visualization, Validation, Supervision, Data curation, Conceptualization.

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