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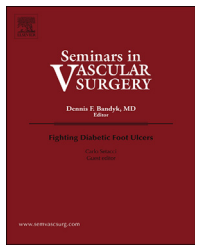

Current status of treatment for aortic graft infection: When should cryopreserved allografts be used?

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ABSTRACT

Aortic graft infection remains one of the most complex clinical challenges faced by vascular specialists, and is often associated with significant patient morbidity and mortality regardless of the approach used for management. The cryopreserved aortic allograft is now a commonly used in situ aortic replacement in the management of graft infection, and is preferred over rifampin-soaked prosthetic grafts. In the review, we summarize the indications for cryopreserved aortic allograft usage, as well as operative technique, clinical results, and alternative treatments. We propose the use of a novel term *tertiary aortic fistula*, to distinguish aortic fistulae in the setting of aortic endograft infection, a clinical entity whose natural history and best management are currently being characterized.

1. Introduction

Abdominal aortic graft infection occur in 1% to 4% of aorta prosthetic grafting procedures [1,2]. These infections have traditionally been treated by extra-anatomic bypass with resection of the infected aortic graft segment [3–5]. Recently, this operative paradigm has been challenged by observational data showing superior outcomes with in situ aortic reconstruction [4,5]. However, there are no prospectively randomized trials comparing surgical approaches to aortic infection. The two primary choices for in situ aortic reconstruction are a prosthetic graft with or without antimicrobial treatment [6] or a biological graft that is allogeneic [7,8], autologous [9,10], or xenogeneic [11].

Modern vascular allograft animal experimental reports by Watts [12] and Carrel [13] date back to the early 20th century, with the first human aortic allograft implants attributed to Gross [14]. DeBakey et al [15] described the use of an aortic allograft in their landmark description of aortic occlusive disease repair in 1954, and the popularity of the fresh aortic allograft as an in situ aortic repair waxed and then waned over 2 decades due to concern for late allograft aneurysmal degeneration [16,17].

Recently, cryopreserved aortic allografts (CAAs) have been shown to be viable conduits for repair of the infected aorta in human and experimental models, either in the presence or absence of prosthetic graft material (Fig. 1). CAAs demonstrate several benefits over fresh allografts, including a lower rate of aneurysmal dilation, which is thought to be due to the preservation of viable fibroblasts that produce collagen and are capable of continuous self-repair [18]. In fact, recent reports cite a negligible rate of aneurysmal dilation and spontaneous CAA degeneration in medium-term follow-up [19]. Furthermore, thicker-walled CAAs are preferred to vein allografts with thin walls, as they better withstand aortic systemic pressure and are more resistant to reinfection and anastomotic disruption [18].

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Another benefit of CAAs is their immediate availability without the need for autogenous tissue harvest (Fig. 2). CAAs may be collected and maintained locally at institutions where organ harvest is performed routinely, or they may be obtained commercially for delivery, usually within 1 day. When stored on site, CAAs remain viable for years and therefore may be used in emergent cases. In contrast, the harvest of deep femoral veins for aortic reconstruction is a time-consuming procedure that significantly increases operating time unless a second surgical team is employed.

In the United States, CAAs (CryoLife, Inc, Kennesaw, GA) are routinely stored at −180°C to −196°C after treating the cadaveric graft with vancomycin, lincomycin, and dimethyl sulfoxide. Graft thawing involves sequential immersion of the graft in solutions of decreasing dimethyl sulfoxide concentration at 37°C to 42°C. Matching of blood and tissue compatibility between the cryografts and recipients is unnecessary [20] and not routinely performed in the United States. In contrast to CAAs utilized in the United States, European centers have historically had considerable variability in CAA preparation and maintenance. Recently, however, European centers have achieved improved clinical outcomes with protocolized CAA preparation and storage in centralized tissue banks [19].

2. Clinical results of cryopreserved aortic allografts for aortic graft infection

A recent meta-analysis [5] of 36 studies on the topic of in situ reconstruction for aortic graft infection included eight reports [7,8,17,21–25] that focused primarily on CAA repair. The meta-analysis supported the use of in situ over extra-anatomic revascularization, although there was no superior conduit identified. CAAs were found to have an aggregate 30-day mortality of 22%, significantly higher than mortality after rifampicin-soaked prosthetic graft (12%) and autogenous vein graft (10%) repairs. However, these results must be interpreted with caution, as some of the studies in the meta-analysis included fresh (not cryopreserved) allografts and immunosuppressed patients [17,22].

There are several high-quality multi-institutional studies from the United States that describe the use of CAA for in situ implantation during abdominal aortic repair. The US Cryopreserved Aortic Allograft Registry has reported results of 56 patients from 31 US institutions with a 30-day mortality of 13% and an overall mortality during the 5.3-month mean follow-up period of 30% [17]. The indication for CAA was aortic graft infection (n = 43), mycotic aneurysm (n = 7), or prior aortic graft reconstruction with infection involving the bowel (n = 6), including 4 patients with aortoenteric erosion or fistula. No patient had a prior aortic endograft; 59% of patients were found to have blood cultures or intraoperative cultures positive for infection, the majority of which were *Staphylococcus aureus* (52%). Graft-related morbidity was 40% among patients who had urgent or emergent CAA repair compared with 24% in the elective group. There were 3 (5%) amputations, 5 (9%) hemorrhages, 5 (9%) graft occlusions, and 0 reinfections noted during the follow-up period.

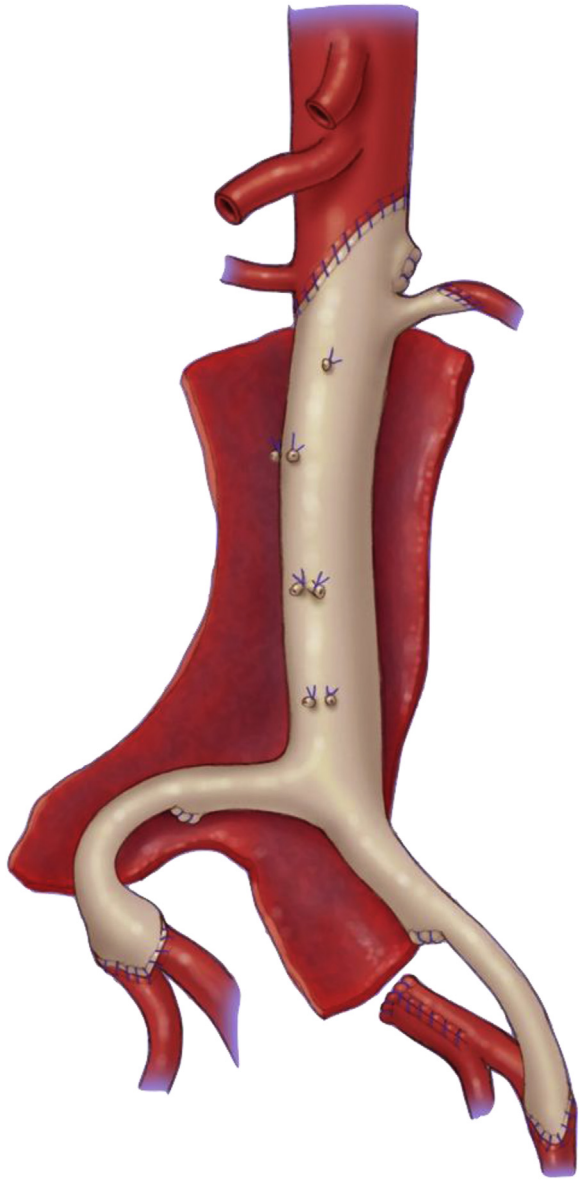

Fig. 1 – In situ aortic reconstruction using bifurcated cryopreserved aortic allograft. Of note, there is a beveled proximal anastomosis, anterior orientation of lumbar artery remnants, and right graft renal artery to native left renal artery anastomosis.

Another multi-institution report from the United States involved 42 patients who received CAAs between 1999 and 2004 for primary aortic graft infection (88%), mycotic aneurysm (22%), or aortoenteric fistula (5%), also demonstrated a 30-day mortality of 17% and overall mortality of 21% in 1-year mean follow-up [26]. Again, *S. aureus* was the predominant microorganism identified. Complications occurred in 50% of patients, including 14% undergoing amputation, with a 2% graft occlusion rate and 21% reinfection rate.

A single US institution observational report of 21 patients who underwent CAA repair between 2001 and 2008 found no deaths in the 4-year median follow-up period [27]. Another single US institution report of 52 cryopreserved arterial repairs

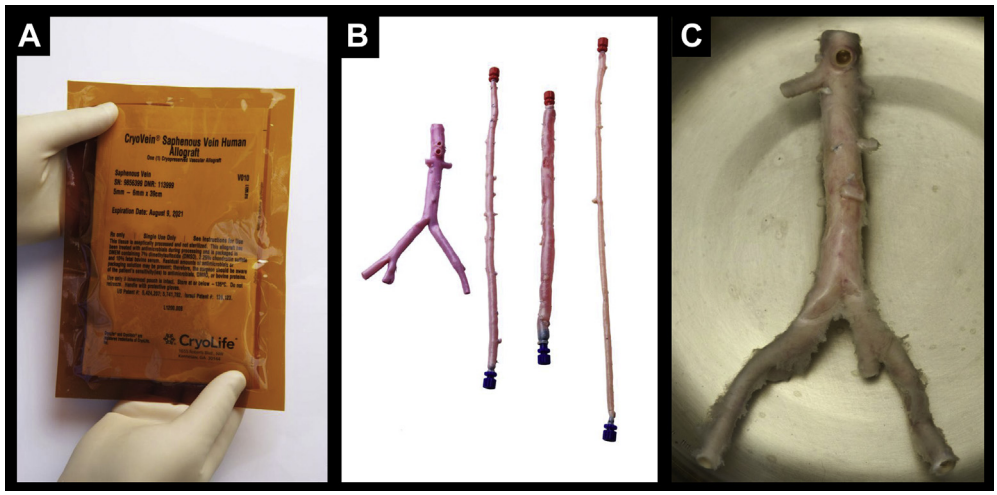

Fig. 2 – Packaging and ex vivo preparation of cryopreserved allografts. (A) Representative packaging of commercially available allograft. (B) Thawed segments of allograft. (C) Aortic allograft soaking in thawing solution.

for aortic or iliopopliteal infections between 1999 and 2008 found 30-day mortality of 5.2% and 1-year mortality of 7% [28]. Interestingly, the report describes a second cohort of 53 patients who simultaneously underwent non-cryopreserved arterial allograft repairs for infected large arteries and the 30-day mortality was similar at 7.5%, although the 1-year mortality was 13%. During 20-month follow-up in the cryopreserved arterial allograft repair group, 9.6% developed hemorrhage or anastomotic disruption, 1 patient developed graft thrombosis, 1 developed recurrent ilioenteric fistula, and 1 required amputation.

European CAA in situ aortic reconstruction has been shown to have similar results compared to those reported from the United States. One single-institution report noted a 30-day mortality of 17% and a commensurate mortality risk of 65% in the presence of aortoenteric erosion or fistula [21]. Another European observational report involving 28 patients with cryopreserved aortic allograft repair for primary abdominal aortic infection or prosthetic graft infection found a perioperative mortality of 17.8% and overall 3-year survival 67% [29]. Among the patients studied were 7 secondary aortic graft-enteric fistulas and 46% of patients underwent emergency procedures. There was no persistent or recurrent infection, and none of the patients received long-term (longer than 3 months) antibiotic therapy. Another recent European study of 71 patients who underwent CAA repair of infected aortic graft reported a perioperative mortality of 16.9% and overall survival rate of 54% during 45 months of follow-up with no aneurysm or dilation observed [19].

While some studies, primarily from the United States, report low postoperative mortality and reinfection rates, others are concerning for substantial graft-related complications. One report of 54 patients who underwent CAA aortic reconstruction for native aortic infection (31%) or prosthetic graft infection (69%, including seven aortoenteric fistulae) noted a 30-day mortality of 28% and postoperative complications occurred in 52% of patients during the 1-year follow-up period [25].

One explanation for these disparate results may be regional differences in CAA preparation, which are less centralized and less standardized outside the United States. The proportion of primary aortic infections or endograft infections in these studies may also be a contributing factor to poor outcomes. These pathologies likely have different natural histories and responses to treatment compared to infections of prior open aortic repair with prosthetic bypass.

2.1. *Endovascular aortic graft infection repair with cryopreserved aortic allograft*

The initial type of aortic repair may prove to be an important risk factor in the treatment of aortic reconstruction, and recent reports from the United States and Europe have published results of CAA repair in the setting of an infected aortic endograft. CAAs have been described in the repair of infected aortic endografts with infrarenal and suprarenal fixation (Fig. 3). In the United States, one report of 180 patients with infected abdominal aortic endografts (endovascular aneurysm repair) included 51 patients who were treated with CAA repair [30]. Perioperative mortality was 7% and overall survival was 72% at 5 years for the CAA group, which also included 3 thoracic aorta endograft (thoracic endovascular aneurysm repair) infections (Table 1). CAA compared favorably against all treatment options, including extra-anatomic bypass, prosthetic in situ repair and neo-aortoiliac system in situ (NAIS) repair. Among CAA repairs, there were no graft thromboses or hemorrhages. In this report, CAA and NAIS repairs appeared to be superior to prosthetic in situ and extra-anatomic repairs, although the authors posited this may be due to surgeon preference for prosthetic repair during emergency cases. Of note, 11% of all patients presented with rupture and 27% of all patients were found to have an aortic fistula at the time of presentation, both associated with higher mortality.

A European multi-institution report of 33 patients with infected abdominal aortic endografts included 23 (69%) with CAA repairs [31]. Among all patients there was a 39% perioperative mortality and a 44% survival at 1-year follow-up. Similar to the US report of infected aortic endografts,

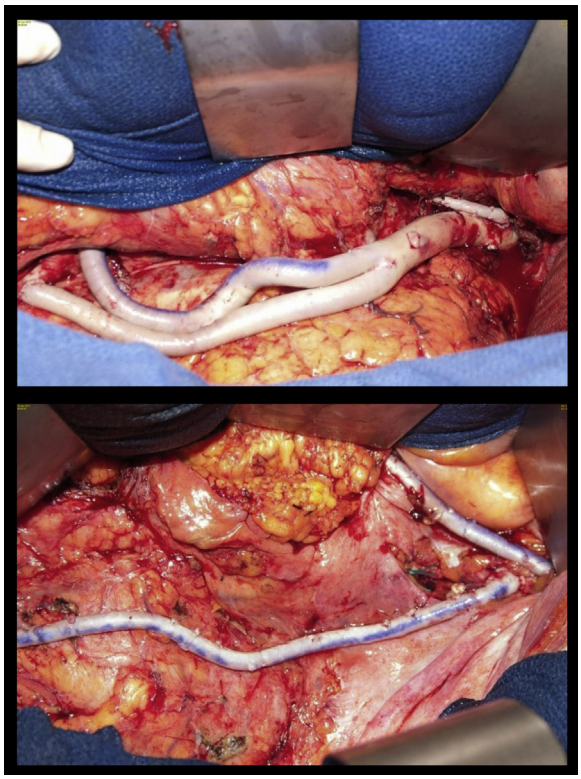

Fig. 3 – Cryopreserved aortic allograft used for in situ thoracobiiliac bypass with femoral allograft extension via left retroperitoneal exposure.

approximately one-third (36%) of patients presented with aortoenteric erosion or fistulae, and the plurality of microorganisms identified were *S. aureus* or *Staphylococcus epidermidis*; 10% of patients experienced graft-related complications and 5% experienced reinfection.

2.2. *Cryopreserved aortic allograft repair of primary, secondary, and tertiary aortic erosion and aortic fistulae*

CAAs have been shown to have mixed survival and reinfection rates in the setting of aortic erosion or aortic fistula, and thus deserve special attention. It is essential to understand that patients with and without aortic fistulae are frequently combined for analysis in the aortic graft infection literature, which may not be appropriate, considering the known morbidity and mortality differences between these two populations. For example, the authors of one study concluded equivalent effectiveness of CAA and silver-impregnated Dacron aortic infection repairs with impressive 9% 30-day mortality and 0% reinfection rates in 3 years, despite the CAA group containing 50% aortic fistulae [32]. In contrast, another study reported an abysmal 28% perioperative survival and high complication rate, especially among aortic fistulae repairs [25]. Considering the heterogeneity of the observational data currently available, a recent meta-analysis appropriately recommended CAA or antimicrobial-treated prosthetic grafts for in situ aortic reconstruction in the setting of aortic fistulae [5].

CAAs have also been shown to have mixed results in the repair of aortic endografts, with a 7% to 39% perioperative mortality and <10% reinfection rates [30,31]. Aortic fistulae associated with aortic endograft infection are anatomically distinct from primary and secondary aortic erosion or fistulae, and seem to be especially morbid, given the available data. We believe this new clinical entity merits a new classification description and we propose a new term, *tertiary aortic fistula*, to distinguish these fistulae in the literature.

2.3. *Reinfection*

CAA repair has been shown to be effective in experimental models of aortic infection. In one study, 23 dogs underwent infrarenal aortic replacement using gelatin-sealed knitted polyester grafts inoculated with *S. epidermidis* [33]; 18 animals survived at 1 week and underwent in situ repair, and antibiotic-treated CAA repair (n = 6) was shown to have significantly decreased inflammation with less infection compared to treatment with new gelatin-sealed prosthetic (n = 6) or non-antibiotic-treated CAA (n = 6). The aortic allograft cryopreservation technique (−190°C to −100°C) itself has also been shown to yield superior *S. aureus* resistance compared with preparation using refrigeration (4°C) in a dog model [34], with superior long-term storage potential [24] and equivalent re-infection rates compared to refrigerated allografts in humans [24,35].

Most CAA studies include microbiological data, but there are few that report individual responses to highly virulent organisms, including antibiotic-resistant species. In most studies, the plurality of patients had no microorganisms found in blood culture or intraoperative culture, presumably attributable to preoperative intravenous antibiotic treatment.

Table 1 – Operative and mortality data summary following repair of infected aortic endograft.

Variable	Extra-anatomic bypass (n = 11)	Prosthetic (n = 111)	CAA (n = 54)	NAIS (n = 21)
EBL, mL, mean ± SD	3,909 ± 1,539	4,142 ± 524	3,588 ± 374	4,986 ± 752
Operative time, min	320 ± 99	359 ± 22	502 ± 54	543 ± 38
Perioperative mortality, n (%)	2 (18)	14 (13)	4 (7)	2 (10)
Overall survival during 5-year follow-up, %	50	53 (antibiotic soaked) 12 (no antibiotic soak)	72	65

Adapted from Smeds MR, Duncan AA, Harlander-Locke MP, et al. Treatment and outcomes of aortic endograft infection. J Vasc Surg 2016;63:332–40 [30].
Abbreviations: CAA, cryopreserved aortic allograft; EBL, estimated blood loss; NAIS, neo-aortoiliac system in situ; SD, standard deviation.

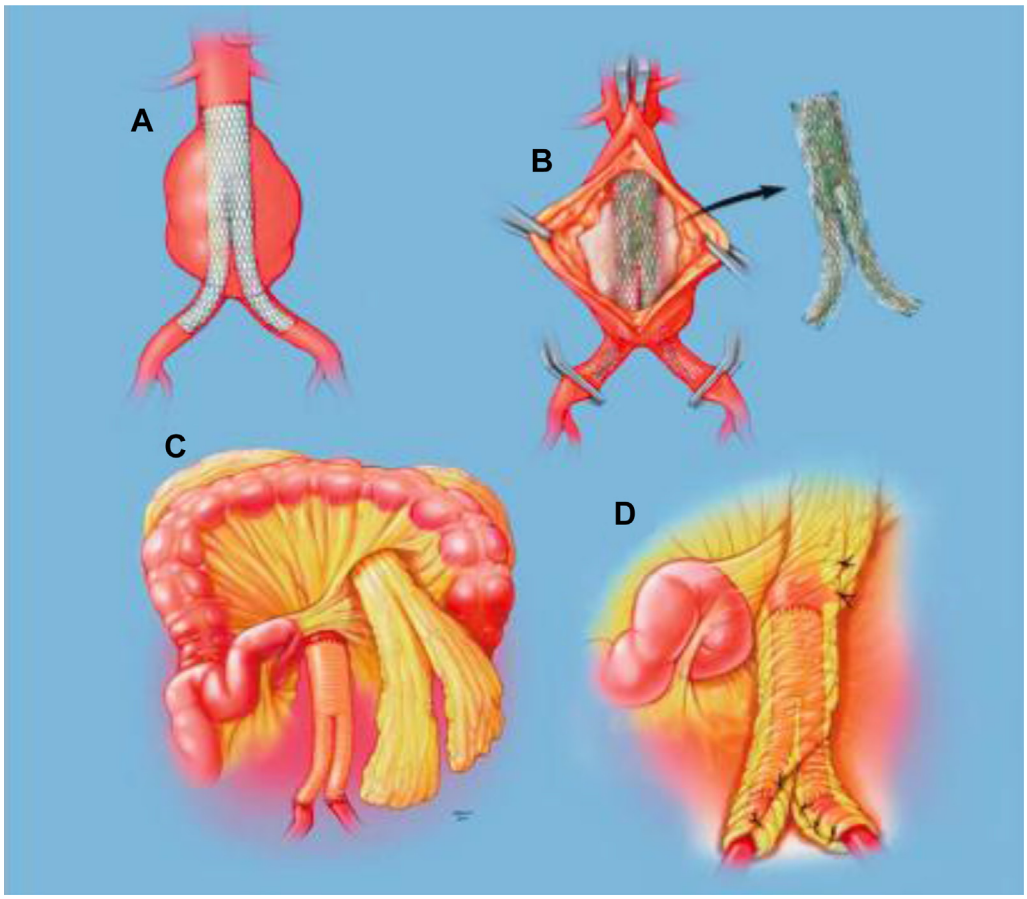

Fig. 4 – Complete removal of infected aortic endograft with in situ aortic reconstruction using cryopreserved aortic allograft repair and omentoplasty. (A) Initial infrarenal aortic endograft. (B) Infected endograft and surrounding infected tissues are excised. (C) Cryopreserved aortic allograft is utilized for an in situ aortobiiliac bypass. (D) Omentum is tunneled through the transverse mesocolon and wrapped circumferentially around the allograft to decrease the risk of infection.

The most predominant species in almost all CAA reports is *S. aureus*, representing approximately 25% to 50% of patients [7,32]. In medium-term follow-up studies, CAA has been demonstrated to be highly effective in patients with aortic graft [32] and non-aortic peripheral graft [36] *Pseudomonas* infection, but retrospective aortic reconstruction data may be biased by surgeon preference for prosthetic grafts in emergency settings due to familiarity and immediate access. Some studies report CAA use in up to 41% of emergency cases, with excellent outcomes and low reinfection rates [32,36].

More recent data comparing different surgical repairs for endograft infection suggest there is no difference in outcomes between patients with Gram-positive and Gram-negative bacteria, although patients with polymicrobial infections have worse outcomes [30]. Patients with CAA repair in the setting of thrombocytopenia are also thought to be at greater risk of reinfection due to the relatively lower concentration of platelet-derived antibacterial peptides specifically against *S. aureus* [31]. Antibiotic treatment of the thawed CAA appears to correlate with higher survival and lower rate of infection [18,32].

Antibiotic treatment duration is also an active area of investigation. Patients with ongoing presence of the pathogenic microorganism postoperatively have a mortality rate >40% and are at higher risk of sepsis-related multiple-organ failure [32]. Expert opinion has classically recommended 4 to 6 weeks of intravenous antibiotics for aortic graft infection [1], although some series report abbreviated or extended courses. For example, patients at the Mayo Clinic remain on lifelong suppressive antibiotics after CAA. Antifungal treatment for 3 months postoperatively has also been suggested to reduce reinfection risk [18]. New data forthcoming should clarify optimal duration of antimicrobial therapy for each type of operative repair.

2.4. *Technical recommendations*

Technical factors have been shown to be related to mortality and overall treatment success in the repair of aortic pathology using CAA. Surgeons should be aware that allograft-patient crossmatching is unnecessary due to the absence of blood group antigens on the CAA [20]. Antibiotic impregnation of the thawed CAA using neomycin immediately prior to implantation has been shown to be associated with very low rates of reinfection and antibiotic toxicity [32]. Tissue coverage of in situ aortic reconstruction using omentoplasty or pedicled muscle transfer is recommended whenever possible [6] (Fig. 4). In one report of 49 patients, the authors concluded

Table 2 – Technical recommendations for successful implantation of cryopreserved aortic allograft.

Recommendation
Elimination of friable allografts
Proper timing of allograft thawing
Ligature of allograft side branches by using a through-and-through polypropylene suture holding of the allograft wall
Enlargement of the anastomotic heel in allograft-to-prosthetic graft anastomosis after partial allograft replacement
Avoidance of any exudate collections around allografts by means of aggressive wound drainage
Circumferential anastomotic reinforcement with allograft strips
Antibiotic treatment of the CAA prior to implantation
Gentamycin-impregnated fibrin glue covering all allograft anastomosis
Autologous tissue coverage with omentoplasty and/or muscle tissue transfer
Avoidance of endovascular interventions within CAA lumen
Antifungal treatment at least 3 months postoperatively
Extended-duration targeted intravenous antibiotics
Rotating the graft with lumbar artery remnants oriented anteriorly to prevent bleeding
Anastomosis of CAA mesenteric branches to native renal arteries (or vice versa)
Accurate sizing without anastomotic tension (CAA cannot be stretched, in contrast to prosthetic grafts)
Use small needles, do not tear CAA

Adapted from Vogt PR, Brunner-LaRocca HP, Lachat M, et al. Technical details with the use of cryopreserved arterial allografts for aortic infection: influence on early and midterm mortality. J Vasc Surg 2002;35:80–6 [37].
Abbreviation: CAA, cryopreserved aortic allograft.

that technical modifications decreased 30-day mortality rate from >10% to 2.6% and eliminated allograft-related late death [37] (Table 2).

In our experience, CAAs viability is not compromised after several years of on-site storage. Furthermore, multiple CAAs can be combined if additional length is required, such as with the use of cryopreserved femoral extensions (Fig. 3). Although the upfront expenses of CAAs are considerable, the reduced operating room time and utilization of the above strategies can reduce overall hospital costs, as well as mitigate long-term costs due to reduced need for secondary procedures. CAAs are particularly attractive for treatment of aortic graft infection when an emergent repair is needed because CAAs can be immediately available, and there are often a limited number of surgeons available to perform the procedure, so the use of multiple teams, often needed for neo-aortoiliac procedures, is not feasible.

3. Conclusions

CAA in situ aortic reconstruction has been shown in several US and European observational series to be a safe and durable option for treating infected primary aortic grafts and mycotic aneurysms. The literature to date has repeatedly shown that 30-day and overall survival rates after CAA repair are comparable to other types of operative repair, with low rates of reinfection for virulent pathogens, including *Staphylococcus* and *Pseudomonas* species. Recent data from the United States also supports the use of CAAs in the setting of infected aortic endografts, especially considering the higher rate of aortoenteric fistula in this patient population. CAAs usually provide an excellent anatomic match for recipients, and may save time in the operating room.

Disadvantages of CAA are also important to note. Successful CAA implant is contingent upon several factors, including timely access to the allograft. Infected aortae or aortic grafts often require emergent operative repair and thus the CAA must be prestocked, rapidly thawed, and washed per protocol by experienced staff. Logistical considerations notwithstanding, data have shown acceptable outcomes and low reinfection rates if a CAA is used in the emergent setting. Also, the cost of CAAs is significantly greater than prosthetic grafts, estimated to be three times more expensive than prosthetic grafts with antimicrobial treatment [32]; however, this may be offset by faster operative times compared to the NAIS procedure and reduced reoperations for infection compared to prosthetic repairs. Although there is minimal published experience, endovascular interventions within previously implanted CAA are discouraged due to CAA inflammation and destruction [37].

In sum, there is no type of in situ repair that has been shown to be definitively superior. In order to attain durable intervention-free survival, there are many variables that one must consider when selecting an operative repair for infected aortic graft. Advanced patient age and preoperative comorbidities have been shown to be associated with poor outcomes, and these patients may benefit from a faster, less morbid operation [5]. The type of infected aortic graft (ie, open graft versus endovascular) and duration of implant time may also have significance. The presenting symptoms, extent of infection, and microbiological data are also important. Emergent aortic reconstruction and the presence of aortic erosion or fistula are possibly the most influential variables and portend poorly. We also propose a new clinical term *tertiary aortic fistula*, defined as an aortic fistula associated with an infected aortic endograft. Ultimately, the best treatment for an infected aortic graft depends on each patient's unique situation.

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