The use of cryopreserved aortoiliac allograft for aortic reconstruction in the United States

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Background: **Aortic infections, even with treatment, have a high mortality and risk of recurrent infection and limb loss. Cryopreserved aortoiliac allograft (CAA) has been proposed for aortic reconstruction to improve outcomes in this high-risk population.**

Methods: **A multicenter study using a standardized database was performed at 14 of the 20 highest volume institutions that used CAA for aortic reconstruction in the setting of infection or those at high risk for prosthetic graft infection.**

Results: **Two hundred twenty patients (mean age, 65; male:female, 1.6/1) were treated since 2002 for culture positive aortic graft infection (60%), culture negative aortic graft infection (16%), enteric fistula/erosion (15%), infected pseudoaneurysm adjacent to the aortic graft (4%), and other (4%). Intraop cultures indicated infection in 66%. Distal anastomosis was to the femoral artery and iliac. Mean hospital length of stay was 24 days, and 30-day mortality was 9%. Complications occurred in 24% and included persistent sepsis (n = 17), CAA thrombosis (n = 9), CAA rupture (n = 8), recurrent CAA/aortic infection (n = 8), CAA pseudoaneurysm (n = 6), recurrence of aortoenteric fistula (n = 4), and compartment syndrome (n = 1). Patients with full graft excision had significantly better outcomes. Ten (5%) patients required allograft explant. Mean follow-up was 30 ± 3 months. Freedom from graft-related complications, graft explant, and limb loss was 80%, 88%, and 97%, respectively, at 5 years. Primary graft patency was 97% at 5 years, and patient survival was 75% at 1 year and 51% at 5 years.**

Conclusions: **This largest study of CAA indicates that CAA allows aortic reconstruction in the setting of infection or those at high risk for infection with lower early and long-term morbidity and mortality than other previously reported treatment options. Repair with CAA is associated with low rates of aneurysm formation, recurrent infection, aortic blowout, and limb loss. We believe that CAA should be considered a first line treatment of aortic infections. (J Vasc Surg 2014;59:669-74.)**

Aortic graft infections are rare, occurring in 0.2%-5% of open aortic reconstructive cases, and they occur less frequently with endovascular aortic procedures.[1-3] These infections, when they occur, may lead to graft/arterial interface disruption, recurrent hemorrhage, or sepsis, and are associated with significant morbidity and mortality.[4] The treatment of patients with aortic graft infection is one of the greatest challenges in vascular surgery, and has led to many alternative methods of treatment, which are often complex procedures, such as graft excision with extra-anatomic bypass, in-line reconstruction with antibiotic soaked prosthetic grafts, and a neo-aortoiliac system procedure using femoral vein. These procedures are often associated with significant complications such as recurrent graft infection, aortic stump blowout, or severe leg edema.[5]

The use of allografts to provide in-line reconstitution of aortic graft infection and aortic procedures at high risk for graft infection has been advocated, due to their resistance to infection.[6-8] In addition, the presence of branch vessels on cryopreserved aortoiliac allograft (CAA) provides conduits for complex renal or mesenteric bypass procedures, which may reduce the mortality of these procedures. However, there are a limited number of small series and case reports on the use of cryopreserved aortic allografts, and it is unclear whether allograft vein or artery is the preferable conduit. The purpose of our study was to (1) evaluate the safety and efficacy of CAA for in-line aortic reconstruction in patients at high risk for or with aortic graft infection, and (2) evaluate the United States' experience with CAA for aortic reconstruction using a standardized, multi-institutional database, which provides a large cohort of patients for analysis.

METHODS

Initial single-institution experience. We developed a database of demographic, comorbid, preoperative imaging, operative, pathologic, perioperative, and follow-up outcomes

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data for patients with a history of abdominal aortic reconstruction who underwent in-line aortic reconstruction with CryoArtery Aortoiliac Arterial Allograft (CryoLife, Inc, Kennesaw, Ga) at the University of California Los Angeles (UCLA). The University of California Los Angeles Institutional Review Board approved the database and study methods.[9]

Multi-institution database development. Our existing UCLA database was modified, based on the input of the coauthors, to capture additional details regarding prior aortic operations, organism type and species, and diagnostic modalities.

Invitations to participate in a multi-institutional study were then sent to the institutions and surgeons with the largest experience with CAA, based on distribution records maintained by the company that processes the CAA. Those surgeons and institutions expressing an interest in participating directly contacted the UCLA study team (14 of the top 20 users of CAA since its introduction) and were sent "study packages" that included a literature review, UCLA's published experience, a study-specific proposal with information needed to aid in institutional review board approval (often expedited), methods to de-identify the patients and data prior to sending it to a central server, and the data collection worksheet. All participants were assisted in obtaining institutional review board approval at their institution by members of the UCLA study team, who also provided collaborative support throughout the entire study and had regular communication with each institution and most surgeons. Data sources for collection were left to the discretion of each institution and included, but were not limited to medical and hospital records, office charts, institutional research databases, billing records, public death registries, and verbal follow-up with patients. Appropriate International Classification of Diseases, Ninth Revision and current procedural terminology codes for aortic graft infection management were provided to each institution to assist in finding patients who were treated with CAA for aortic graft infection over the study period.

Database management. After appropriate study approval was obtained at each institution and hospital, patient data was collected by each surgeon and institution and transmitted to the study team. Data was stored in a password-encrypted central database on a UCLA server and managed by the Division of Vascular Surgery at the University of California Los Angeles. The study team and principal investigator reviewed all patient data for accuracy and completeness as it was received; incomplete entries and data-entry errors were resolved with each institution's principal investigator by the UCLA study team.

Statistics. All data was managed and retained in a Microsoft Excel (v. 14; Microsoft Corp, Redmond, Wash) database. Analysis was performed using SPSS Statistics for Mac (v. 20.0; IBM Corporation, Armonk, NY). Kruskal-Wallis analysis of variance testing and Tukey b post hoc testing were performed for determination of operation frequency and outcome independence. Categorical variables are presented by frequency and percent of study population; continuous variables are presented as mean ± standard error of mean, unless noted otherwise. Differences and level of significance between groups for categorical variables were determined using the χ^2 test or Fisher exact test. Differences for continuous variables were analyzed using the independent *t*-test or Mann-Whitney *U* test. Multivariable outcome analysis was performed using binary and multinomial logistic regression models. Cochran and Mantel-Haenszel methods were used for hazard ratios (HRs) and 95% confidence intervals (CIs). Patient survival and freedom from limb loss were analyzed using Kaplan-Meier Life Table methods. A *P* value of <.05 was considered significant.

Table I. Initial aortic procedure indications

Indication	*No.*	*% of total patients*
Abdominal aortic aneurysm	165	75
Suprarenal	6	
Infrarenal	159	
Occlusive disease	51	23
Aortic	9	
Aortic + iliac(s)	42	
Trauma- aorta	2	1
Atheroembolism from aorta	1	.5
Iatrogenic aortic injury	1	.5
Type of procedure		
Open reconstruction	209	95
Endovascular	11	5

RESULTS

Patients were treated at 14 of the 20 highest-volume institutions from different regions of the United States that use CAA (Appendix, online only). Two hundred twenty patients underwent in-line aortic reconstruction with CAAs (male:female = 1.6/1); mean age was 65 ± standard deviation 12 (range, 31-91 years). Indications for use of CAA included culture positive aortic graft infection (n = 133; 60%), culture negative aortic graft infection (n = 36; 16%), graft enteric fistula/erosion (n = 33; 15%), infected pseudoaneurysm adjacent to the aortic graft (n = 9; 4%), and other (n = 9; 4%), including trauma, increased risk of graft infection, low flow axillo-bifemoral bypass with pelvic ischemia, and recurrent prosthetic graft thrombosis. Indications and techniques for the initial aortic surgery can be seen in Table I. One hundred twenty-two of the original grafts were aortic tube (55%), 66 were bifuricated aortoiliac (30%), and 32 were bifuricated aortofemoral (15%). The mean time between the initial prosthetic aortic graft procedure and CAA implant was 7 ± 1 months (range, 1-22 months).

Risk factors and comorbidities. Risk factors for aortic surgery included hypertension (n = 144; 66%), smoking (n = 118; 54%), diabetes mellitus (n = 55; 25%), immunosuppression (n = 10; 5%), and connective tissue disorder (n = 2; 1%). Patient comorbidities were peripheral arterial disease (n = 91; 41%), prior myocardial infarction (n = 44; 20%), prior stroke (n = 18; 8%), prior major (n = 14; 6%) and minor amputation (n = 6; 3%), and congestive heart failure (n = 13; 6%).

Operative data. One hundred sixty-three patients (74%) underwent elective CAA replacement surgery; 57 (26%) were treated emergently with surgery. The mean American Society of Anesthesiologists score for all patients was 3.3 ± 0.1; the mean for elective cases was 3.0 ± 0.1 and 3.4 ± 0.1 for emergent cases. The mean length of operation and estimated blood loss was 464 ± 19 minutes and 2051 ± 159 mL, respectively.

Full excision of a prior graft was performed in 149 patients (68%) and partially excised in 71 patients (32%). The proximal anastomosis was performed to the infrarenal portion of the aorta in 214 patients (97%), the suprarenal aorta in four patients (2%), and the supraceliac aorta in two patients (1%). The distal anastomosis (end-to-end, n = 160; 73%; end-to-side, n = 60; 27%) was performed bilaterally to the femoral artery (n = 139; 63%) and iliac artery (n = 66; 30%), and unilaterally to the femoral (n = 15; 7%) and iliac artery (n = 15; 7%). Sartorius myoplasties were used to cover the femoral artery in 17% (n = 37) of reconstructions. Sixty-one patients (27%) required at least one cryopreserved allograft segment to extend the graft to the distal anastomotic site. Additional concomitant vascular procedures included femoral-femoral bypass, angioplasty, and thrombectomy as shown in Table II; four of these procedures involved the use of additional cryopreserved allograft segments for bypass. The results of intraoperative cultures are shown in Table III.

Postoperative data and complications. The mean length of hospital stay was 24 ± 2 days; patients were managed postoperatively with antibiotics for a mean of 48 ± 8 days. Patient outcomes were not dependent on the institutional frequency of the CAA operation performed (P = .722). Procedure-related complications occurred in 24% of patients and included CAA infection, CAA rupture, CAA thrombosis/occlusion, CAA stenosis, CAA pseudoaneurysm formation, aorto-enteric fistula recurrence, new onset of sepsis, and lower extremity compartment syndrome (Table IV). Factors associated with CAA-related complications (31 patients; 14%) were age >70 (HR, 1.657; 95% CI, 1.286-2.512; P = .003), peripheral arterial disease (HR, 2.050; 95% CI, 1.094-4.466; P = .027), and virulent, primarily gram negative, organisms (HR, 2.423; 95% CI, 1.821-3.096; P = .038). Two CAA were explanted at 7 and 15 days due to recurrent infection, diagnosed by imaging and blood cultures (Table V). Patients requiring late interventions underwent successful graft angioplasty (n = 5; 2%) and aortoiliac thrombectomy (n = 2; 1%).

Follow-up data. The mean length of follow-up was 30 ± 3 months (range, 1-160 months). A total of 10 CAA (5%) required explant during study follow-up (Table V). Factors associated with CAA explant were age >70 (HR, 1.390; 95% CI, 1.081-5.883; P = .041) and partial aortic graft excision (HR, 3.222; 95% CI, 1.357-29.054; P = .007). After explant, six patients had an extra-anatomic bypass, three patients had a neo-aortoiliac system procedure, and one patient died intraoperatively. All but the intraoperative death survived. Freedom from graft-related complications was 92% at 1 year and 80% at 5 years (Fig 1), and freedom from graft explant by Life Table analysis was 99% at 1 year and 88% at 5 years (Fig 2). Patient survival by Life Table analysis was 75% at 1 year and 51% at 5 years (Fig 3), and primary graft patency by Life Table analysis was 98% at 1 year and 97% at 5 years and freedom from limb loss was 98% at 1 year and 93% at 5 years (Fig 3).

Table II. Additional procedures performed concomitantly with cryopreserved aortoiliac allograft (CAA) placement

Procedure	*No.*	*% of total patients*
Femoral-femoral bypass	28	13
Angioplasty	14	6
Thrombectomy	12	5
Femoral-popliteal bypass	10	5
Colon resection	4	2
Femoral-popliteal graft replacement with cryovein	4	2
Appendectomy	4	2
Duodenal repair	3	1
Iliac endarterectomy	2	1
Femoral endarterectomy	2	1
Other	12	5

Table III. Organisms identified from intraoperative cultures of resected prior aortic graft

Organism	*No.*	*% of total patients*
Culture negative	75	34
Methicillin-sensitive *staphylococcus aureus*	21	10
Polymicrobial	21	10
Methicillin-resistant *staphylococcus aureus*	14	6
Escherichia coli	13	6
Pseudomonas	10	5
Staphylococcus sp	9	4
Enterococcus sp	8	4
Propionibacterium acnes	6	3
Vancomycin resistant enterococcus	6	3
Streptococcus sp	6	3
Salmonella	4	2
Clostridium	4	2
Klebsiella	4	2
Corynebacterium sp	4	2
Bacteroides sp	4	2
Enterobacterium sp	4	2
Other	7	3

DISCUSSION

This is the largest study of cryopreserved aortoiliac arterial allografts and represents approximately 25% of all

Table IV. Early and late-term postoperative complications

Complication	*No.*	*% of total patients*
Persistent sepsis	17	8
CAA thrombosis/occlusion	9	4
CAA rupture	8	4
Recurrent CAA infection	8	4
CAA pseudoaneurysm	6	3
Aorto-enteric fistula recurrence	4	2
Lower extremity compartment syndrome	1	.5
Colonic perforation	1	.5
Lower limb ischemia	1	.5

CAA, Cryopreserved aortoiliac allograft.

Table V. Indications and duration of cryopreserved aortoiliac allograft (*CAA*) implant for patients requiring CAA explant

Patient	*Indication*	*Duration of CAA implant*
1	CAA infection	73 months
2	CAA infection	51 months
3	CAA aneurysm	40 months
4	CAA stenosis	38 months
5	CAA aneurysm	23 months
6	CAA infection	11 months
7	CAA pseudoaneurysm	10 months
8	CAA pseudoaneurysm	5 months
9	CAA infection	15 days
10	CAA infection	7 days

CAAs placed in the United States since their commercial availability. The conclusions of this study are that CAA allows for in-line aortic reconstruction in the presence of infection, with lower patient morbidity and mortality than the results of other published treatment options for which long-term results are available, and CAA is associated with low rates of aneurysm formation, allograft rupture, recurrent infection, and limb loss.

The mainstay for treating aortic prosthetic graft infections, and less frequent endovascular graft infections, has been extra-anatomic bypass, the neo-aortoiliac system procedure, and unpreserved allograft; however, each of these treatments is associated with high morbidity.[5,10,11] In one of the largest reported series using graft excision and extra-anatomic bypass, Reilly et al reported aortic stump blowout occurring in 25% of patients, amputation in 16%, and a 1-year survival of 73%.[12] Better outcomes have been associated with in situ replacement, eliminating the risk of aortic stump blowout, using either antibiotic soaked prosthetic grafts or a neo-aortoiliac system constructed from femoral veins. Bandyk et al showed that the use of prosthetic grafts resulted in 0% early limb loss while reports of outcomes with neo-aortoiliac system showed 6% early limb loss and an 83% 1-year survival.[13-15] Our study using CAA showed early limb loss in 0%, comparable to the best results of small series with in situ alternatives. Our study also showed that outcomes were significantly better in patients who had full graft excision, compared with patients with partial graft excision, probably due to residual infection in the remaining prosthetic graft.

One of the primary objectives in saving life and limb during graft infection management is minimizing the incidence of recurrent infection. The reported incidence of recurrent infection in large series with graft excision and extra-anatomic bypass is 20%, neo-aortoiliac system is reported to be 13%, and in situ replacement with prosthetic grafts ranges from 10% to 15%.[5,11-13] These incidences are higher than the rates reported by one midsized series with cryopreserved allograft[16]; in our series only eight patients (4%) had a recurrent infection. There is often concern about the virulence of organisms that infect aortic grafts and whether all aortic graft infections and all organisms are appropriate candidates for inline aortic replacement. In our series, patients with virulent organisms had significantly more allograft-related complications but there was no correlation between recurrent infection and the presence of an abscess in the retroperitoneum.

The use of fresh allograft has been discontinued in most institutions due to concerns regarding the graft's propensity to dilate over the long term.[17] The application of current cryopreservation techniques has been shown to preserve the integrity of the collagen matrix, which is believed to be responsible for fewer graft-related complications and higher graft patency rates. The benefit of using cryopreserved allografts is that they are processed so that they do not require ABO matching. In addition, CAAs can be selected to match the normal aorta and its branches in diameter and anatomy and, therefore, are superior to allografts constructed on the back table in the operating room of either cryopreserved vein or femoral artery. Good outcomes have been reported using cryopreserved femoral artery or vein for aortic reconstruction; however, the use of these allografts is time consuming and becomes even more time consuming and complex with involvement of the renal or visceral arteries.[8,18] One of the most advantageous aspects of using CAA is the inclusion of the visceral, renal, and hypogastric side branches, allowing for bypass to vessels to avoid renal, mesenteric, and pelvic ischemia.

The current limitations to our study are that it did not compare the use of CAA replacement with other reconstructive treatment options. However, a multicenter randomized trial would be difficult to conduct with the low volume of cases at each institution. The use of CAAs remains limited in the United States, and despite participation of 14 of the 20 highest volume institutions, many of those institutions contributed less than 10 patients; therefore, the results are as dependent on an individual surgeon's skill and experience as the type of conduit.

CONCLUSIONS

This largest study of CAA indicates that repair with allograft allows in-line reconstruction in the setting of aortic graft infection with lower early and long-term

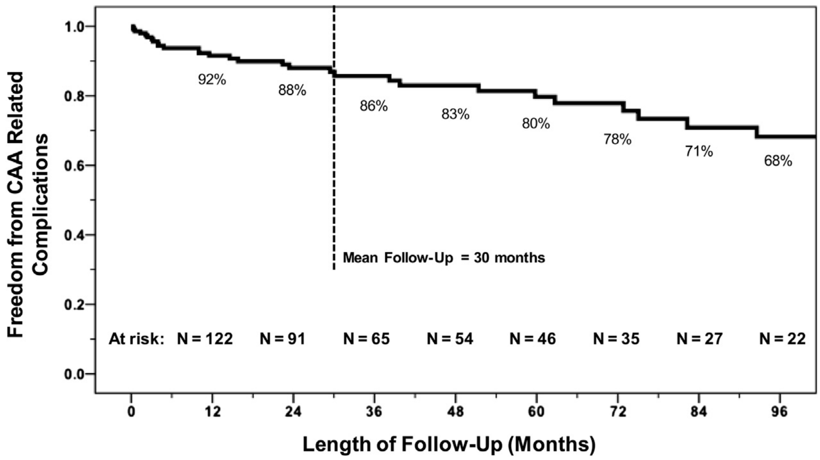

Fig 1. Kaplan-Meier analysis of freedom from cryopreserved aortoiliac allograft (*CAA*)-related complications.

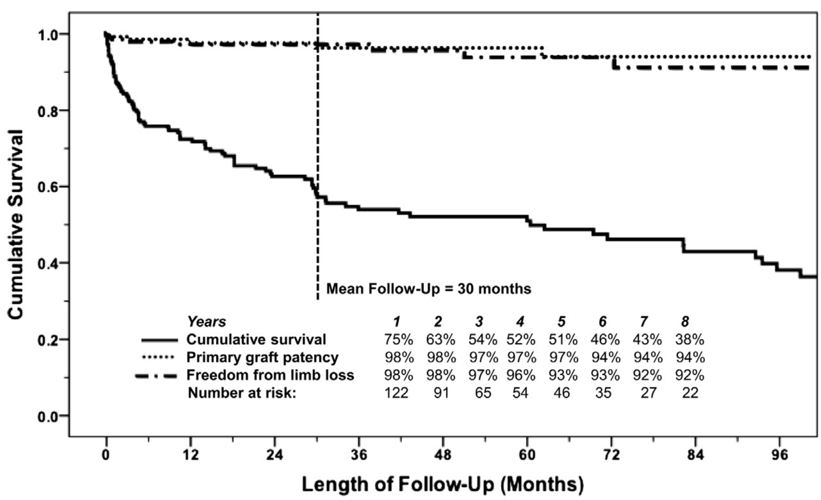

Fig 2. Kaplan-Meier analysis of patient survival, cryopreserved aortoiliac allograft (CAA) primary patency, and freedom from limb loss.

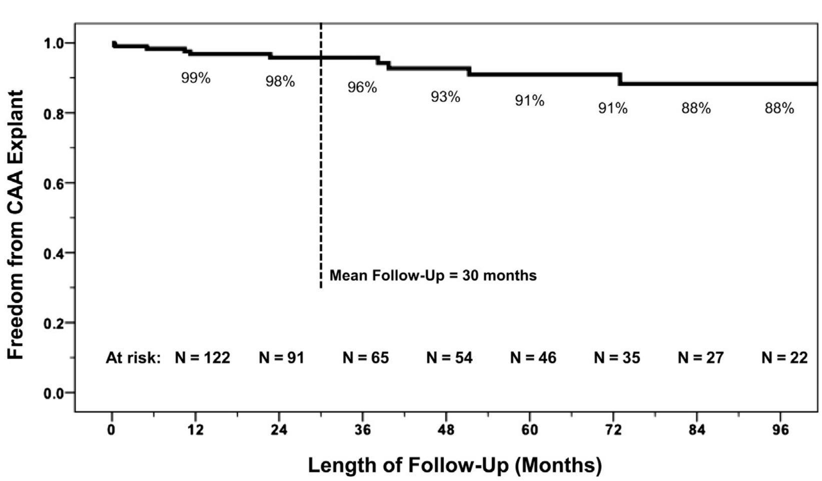

Fig 3. Kaplan-Meier analysis of freedom from cryopreserved aortoiliac allograft (*CAA*) explant.

morbidity and mortality than the results of other published treatment options for which long-term data is available. Its use is associated with infrequent postoperative complications such as rupture, recurrent infection, aneurysm formation, and limb loss, making CAA a preferable alternative to other extra-anatomic or in situ options.

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AUTHOR CONTRIBUTIONS

Conception and design: MH-L, LH, PL
Analysis and interpretation: MH-L, LH, PL, GO, RM, MM, RF
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Writing the article: MH-L, LH, PL
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APPENDIX (online only).

The contributing institutions and number of cases submitted are as follows: Indiana University: 35 patients; Northwestern: 32 patients; Saint Louis University: 28 patients; University of Florida: 25 patients; Stanford Hospital: 16 patients; Methodist Hospital: 16 patients; University of California Davis: 15 patients; University of California Los Angeles: 14 patients; Mayo Clinic: 14 patients; Indiana Ohio Heart: 9 patients; Washington University: 7 patients; Baylor University: 5 patients; William Beaumont Hospital: 3 patients; Advocate Lutheran General Hospital: 1 patient.