Single-center experience with all-biological valved conduit for the treatment of complex aortic root endocarditis

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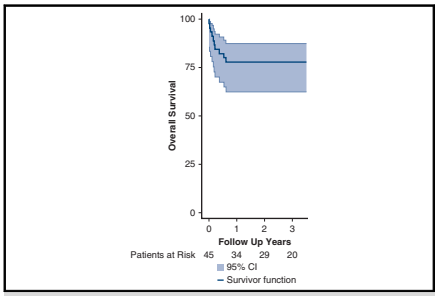
ABSTRACT

Objective: Despite advancement in medical and surgical treatment, endocarditis involving the aortic root still represents a challenge for the cardiac surgeon due to the anatomic complexity and fundamental function of the aortic root itself. The purpose of this research is to assess outcomes from one center's experiences of implementing the BioIntegral conduit for patients who have undergone both aortic root and aortic valve replacement due to complex aortic root infective endocarditis.

Methods: From February 2011 to December 2023, 46 patients underwent BioIntegral valved conduit implantation at our institution. The mean age of our population was 67.6 years (±9.3 years), and the primary surgical indication was severe active endocarditis involving the aortic root. The mean European System for Cardiac Operative Risk Evaluation II was 25.6 (±15.8). We evaluated 30-day mortality, overall survival, and freedom from reoperation as end points of our analysis using *t* tests, chi-square tests, Cox regression, and Kaplan–Meier analyses.

Results: Six patients died during hospital stay (13.0%), and the reported 30-day mortality was 8.2% (4 patients). The Cox regression analysis performed to evaluate the impact of both risk factors and intraoperative attributes on the 30-day mortality rate showed that the variables related to increased 30-day mortality were European System for Cardiac Operative Risk Evaluation II ($P = .045$), older age, and cardiopulmonary bypass time. On Kaplan–Meier analysis, the overall survival at 1 and 3 years was 87.0%, whereas freedom from reoperation for graft dysfunction was 100% and at 1 and 3 years.

Conclusions: Despite the small sample size, our results indicate favorable long-term survivals and minimal need for reoperation with the BioIntegral conduit. This conduit demonstrated positive outcomes even in patients with complex surgical histories and severe aortic root and valve endocarditis. Although promising, these results warrant further investigation with larger patient groups to confirm their broader applicability. (JTCVS Techniques 2025;33:98-103)



Survival at 0, 1, 2, and 3 years after BioIntegral implant for aortic root endocarditis.

CENTRAL MESSAGE

BioIntegral prosthesis for the treatment of complex aortic root endocarditis shows favorable long-term survivals and minimal need for reoperation.

PERSPECTIVE

The results of our study indicate that the BioIntegral conduit can be a viable prosthesis choice in the treatment of complex endocarditis of the aortic root due to its durability and pliability and its total biological structure.

Infective endocarditis, although a rare condition, carries an alarmingly high mortality rate. Its incidence ranges from approximately 1.5 to 13.8 cases per 100,000 individuals annually. Globally, it accounted for 66,300 deaths in 2019, reflecting a mortality rate of 0.87 per 100,000 patients.[1-3] Approximately 1 in 5 cases develops with prosthetic valves or implanted cardiac devices, with prosthetic valve involvement being more common. Infective endocarditis poses a significant surgical challenge, especially when the aortic root is affected. Complications such as abscesses, fistulas, and pseudoaneurysms necessitate prompt and aggressive treatment.[1-5]

Choosing the right graft material is crucial.[6] The primary goals in choosing a graft are to ensure graft durability and to minimize the risk of reinfection, preventing complications

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This retrospective study was approved by the local Institutional Review Board (GDG and DP) and did not require the patient's informed consent (IRB 2021/Disp/AOUBo).

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Abbreviations and Acronyms
CPB = cardiopulmonary bypass
EuroSCORE = European System for Cardiac Operative Risk Evaluation

and the need for future surgeries.[7,8] However, both biological and mechanical valve conduits for root replacement come with the downside of having foreign material within the new annulus and valve.

Although homografts offer promising results in several studies, their limited availability restricts widespread use.[9] Other alternatives exist, including xenografts and Freestyle graft.[10] Xenografts, typically derived from animal tissues such as porcine valves, provide a biocompatible and durable solution that avoids the need for long-term anticoagulation therapy, making them ideal for many patients.[11] The Medtronic Freestyle aortic root bioprosthesis, a stentless porcine valve, offers superior hemodynamics by mimicking natural valve function and facilitating better integration with the patient's native tissue.[12]

The BioIntegral Conduit system, composed of a bioprosthetic valve and graft, closely mimics native aortic tissue, promising improved biocompatibility, reduced risk of thromboembolic complications, and excellent potential for long-term durability in aortic root surgery.[13]

The present study aims to analyze our experience with the implantation of the BioIntegral Bio-Conduit, analyzing 30-day survival time and aortic root–related complications, as well as the need for further reoperations.

MATERIALS AND METHODS

BioIntegral Aortic All-Biological Valve Conduit

Originally produced by Shelhigh Inc, the stentless, entirely biological conduit was retired by the US Food and Drug Administration in 2005 for excessive incidence of pseudoaneurysms and early graft failures. However, the conduit, still meticulously handsewn from a porcine valve and a single layer of bovine pericardium, was revised and reinstated by BioIntegral Surgical Inc. It remains treated with the No-React technology, resulting in aldehyde cross-linkage, aldehyde detoxification, and surface modification through surfactant. In 2013, the BioIntegral conduit received CE marking, making it commercially available for aortic root replacement.

Data Appraisal

An exhaustive analysis was conducted by researching clinical data from the patient records, as well as analyzing the echocardiographic and radiologic data of the same patients. To maintain quality control, all patients routinely received preoperative and postoperative echocardiography. Additionally, patients were assessed in the outpatient clinic and contacted by phone to gather follow-up data, as well as periodic echocardiograms and, possibly, other imaging exams performed such as computed tomography angiography scans.

Statistical Analysis

Categorical variables were outlined as counts and percentages, and continuous variables were presented as averages with SD. The *t* test and chi-square test were used for comparing groups. Survival time throughout observation was calculated with the Kaplan–Meier method. The Cox regression model was used to identify the hazard ratio of risk determinants on the survival time of 30 days. Statistical analyses were conducted using SPSS Statistics v26 (Statistical Package for Social Sciences, IBM).

Surgical Technique

A conventional median sternotomy is performed. Heparin dosages ranging from 250 to 300 IU/kg in body weight are administered to achieve an activated clotting time more than 200 seconds for cannulation and 400 seconds for initiating cardiopulmonary bypass (CPB).

Preference is given to the distal ascending aorta or the aortic arch for arterial cannulation, and venous cannulation is typically carried out at the right atrium (or bicaval). When reentry is particularly challenging or the patient presents with deteriorated hemodynamic conditions, peripheral femoral cannulation is preferred.

After the onset of CPB, the patient is mildly cooled to a temperature of 32 °C. A vent catheter is inserted into the right upper pulmonary vein for left ventricle drainage. In the case of aortic hemiarch and arch replacement, moderate hypothermia (25 °C) and antegrade selective cerebral perfusion are used. Hypothermic crystalloid cardioplegia (Custodiol, Koehler Chemie) is administered selectively in coronary ostia.

After the removal of infected tissues, an extensive and accurate disinfection is conducted with iodine solution, dipping a swab in this solution and carefully applying it to the inner surface of the rim area and the surrounding tissues. Thus, reconstruction of the ventricular-aortic junction (as neoannulus) is performed using stripes of bovine pericardium. The BioIntegral conduit is then implanted using single Prolene 3/0 stitches. According to the modified Bentall "button technique," both coronary ostia are anastomosed to the prosthesis after their complete mobilization using Prolene 5/0 suture. It should be noted that the implantation of the BioIntegral conduit is exclusively reserved for the aforementioned endocarditis involving the aortic root and does not apply to routine aortic valve or aortic root surgeries in our center.

RESULTS

Preoperative Patient Characterization

From February 2011 to December 2023, 46 patients (33 male and 13 female – 71.7%/28.3%, respectively, mean age 67.6 ± 9.3 years) underwent BioIntegral valved conduit implantation at our institution. The primary surgical indication was severe infective endocarditis involving the aortic root. Fifteen patients (32.6%) exhibited signs of local invasion (5 pseudoaneurysms and 12 abscesses – 2 patients presented both). Mean European System for Cardiac Operative Risk Evaluation (EuroSCORE) II was 25.6 ± 15.8, ranging from 4.4 to 74.5. Preoperative characteristics of the patients are shown in Table 1.

Intraoperative Characteristics

Among the totality of 46 cases, 31 operations (67.4%) were conducted under elective regimens, whereas 15 (32.6%) and 3 (6.5%) procedures were performed under urgent and emergency regimens, respectively. A total of 42 cases (91.3%) were reoperations. The preferred arterial cannulation site was the ascending aorta (30.4%), followed by the aortic arch and femoral artery (28.3%), brachiocephalic trunk and axillary artery (4.3%), and left common carotid artery (2.2%). For the venous cannulation site, in

TABLE 1. Demographic parameters and main comorbidities

Variables	Values
Demographics	
Age (y)	67.6 ± 9.3
Female sex, n (%)	13 (28.3)
Body surface area (m^2)	1.7 ± 0.6
Comorbidities	
Systemic hypertension, n (%)	31 (67.4)
Smoking, n (%)	20 (43.5)
Dyslipidemia, n (%)	19 (41.3)
Diabetes, n (%)	8 (17.4)
Chronic kidney disease, n (%)	10 (21.7)
Lung disease, n (%)	2 (4.3)
Cerebrovascular disease, n (%)	11 (23.9)
Peripheral artery disease, n (%)	3 (6.7)
Coronary artery disease, n (%)	11 (23.9)
Acute myocardial infarction, n (%)	3 (6.5)
Bicuspid aortic valve, n (%)	5 (10.9)
Prior cardiac surgery, n (%)	42 (91.3)
EuroSCORE II	25.6 ± 15.8
LVEF <50, n (%)	4 (8.6)
NYHA class III-IV, n (%)	5 (10.9)
Aortic root pathology	
Infective endocarditis, n (%)	46 (100)
Abscess, n (%)	12 (26.1)
Pseudoaneurysm, n (%)	5 (10.9)

Values are reported as mean ± SD or n (percentage). *EuroSCORE*, European System for Cardiac Operative Risk Evaluation; *LVEF*, left ventricular ejection fraction; *NYHA*, New York Heart Association.

TABLE 2. Intraoperative features

Variables	Values
Cardiopulmonary bypass time, (min)	255.7 ± 73.9
Crossclamp time (min)	187.3 ± 35.6
Antegrade selective cerebral perfusion time (min)	68.3 ± 45.6
Cannulation site - artery	
Axillary artery, n (%)	2 (4.3)
Ascendig aorta, n (%)	14 (30.4)
Aortic arch, n (%)	13 (28.3)
Brachiocephalic trunk, n (%)	2 (4.3)
Left common carotid artery, n (%)	1 (2.2)
Femoral artery, n (%)	13 (28.3)
Cannulation site – vein	
Right atrium, n (%)	32 (69.6)
Bicaval, n (%)	4 (8.7)
Femoral vein, n (%)	10 (21.7)
Cardioplegia administration	
Aortic root, n (%)	12 (26.1)
Coronary ostia, n (%)	26 (56.5)
Retrograde, n (%)	8 (17.4)
Associated procedures	
Aortic procedures, n (%)	3 (6.5)
Hemiarch, n (%)	2 (4.3)
Frozen elephant trunk, n (%)	1 (2.2)
Coronary artery bypass graft, n (%)	6 (13.0)
Commando procedure, n (%)	3 (6.5)
Mitral valve repair, n (%)	1 (2.2)
Epicardic pacemaker implantation, n (%)	12 (26.1)

Values are reported as mean ± SD or n (percentage).

most cases the right atrium was cannulated (69.6%), followed by the femoral vein (21.7%) and bicaval cannulation (8.7%). Isolated aortic root replacement was performed on 32 patients (69.6%), and 13 patients (28.3%) underwent combined procedures.

Mean CPB and crossclamp times were 255.7 ± 73.9 minutes and 187.3 ± 35.6 minutes, respectively. Three patients (6.5%) needed circulatory arrest with mean antegrade selective cerebral perfusion time of 68.3 ± 45.6 minutes. Intraoperative characteristics are described in Table 2.

Postoperative Characteristics

The overall in-hospital mortality rate was 13.0% (6 patients): Four patients (8.7%) died within the first 30 days, and 2 patients (4.3%) died during long intensive care unit hospitalization after 30 days. Of these, 1 patient died during surgery, and the other 5 patients died of multiorgan failure. Four patients (8.7%) underwent surgical revision for excessive bleeding (Table 3).

During the 100% complete follow-up period of 3.0 ± 2.2 years, mortality was 19.6% (9 patients). Survivals at 1 and 3 years were 87.0% (Figure 1). Freedom from reoperation at 1 and 3 years was 100% and 93.8%, respectively (Figure 2). Echocardiographic assessment revealed satisfactory valve performance, with reported mean gradients of 14.7 ± 7.5 mm Hg.

Computed tomography angiography scans before discharge identified moderate postoperative pericardial effusion in 25 patients (62.5%). At the 6-month follow-up, the pericardial effusion had persisted in 3 patients, but it was completely resolved in all patients by the 24-month checkup.

To further assess the 30-day mortality rate, we conducted a *t* test and Cox regression analysis to examine the differences between patients who survived and those who did not within 30 postoperative days. The *t* test showed higher EuroSCORE II values ($P < .001$), increased rate of chronic kidney disease ($P = .010$), and presence of abscess ($P < .001$) in the deceased group. On the other hand, no significative differences were noticed concerning intraoperative aspects such as CPB and crossclamp time.

The analysis of postoperative data reported that continuous venovenous hemofiltration, sepsis, and reopening for bleeding were more frequent in the 30-day nonsurvivor group with a statistical significance of $P = .007$, $P = .001$, and $P = .044$, respectively. Further *t* test analysis results are shown in Table 4.

TABLE 3. Perioperative outcomes

Variables	Values
In-hospital death, n (%)	6 (13.0)
Cardiac complications	
Atrial fibrillation/flutter, n (%)	13 (28.3)
Acute myocardial infarction, n (%)	1 (2.2)
Third-degree atrioventricular block, n (%)	5 (10.9)
Ventricular fibrillation, n (%)	3 (6.5)
Cardiogenic shock, n (%)	2 (4.3)
Neurological complications	
Agitation, n (%)	5 (10.9)
Transient ischemic attack or ischemic stroke, n (%)	2 (4.3)
Hemorrhagic stroke, n (%)	1 (2.2)
Respiratory complications	
Prolonged mechanical ventilation, n (%)	10 (21.7)
Pneumonia, n (%)	6 (13.0)
Transient dialysis, n (%)	6 (13.0)
Permanent dialysis, n (%)	1 (2.2)
Sepsis, n (%)	8 (17.4)
Bleeding requiring surgical revision, n (%)	3 (6.5)

Values are reported as mean ± SD or n (percentage).

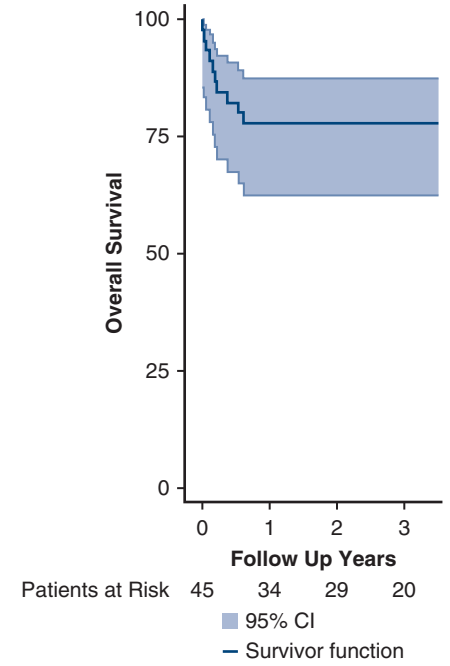

FIGURE 1. Kaplan–Meier analysis displaying overall survival at 0, 1, 2, and 3 years.

A Cox regression analysis was performed to evaluate the impact of both risk factors and intraoperative variables on the 30-day mortality rate. The first model, analyzing demographics, showed that the only variable related to increased 30-day mortality was EuroSCORE II ($P = .003$), whereas age, female sex, diabetes, and chronic kidney disease showed no statistical relation with the outcome. The second model, regarding intraoperative variables, revealed a relation between older age and CPB time with higher 30-day mortality ($P = .046$ and $P = .035$, respectively).

DISCUSSION

Infective endocarditis is a rare but complex disease with high mortality rates. Replacement therapy remains the cornerstone of treatment, sparking ongoing debate about the optimal prosthesis choice. In recent years, studies have compared the outcomes of biological and mechanical prostheses.

A recent study, based on an Italian national registry, examined 549 patients undergoing valve replacement for infective endocarditis. A better survival was observed for patients undergoing mechanical valve implantation, with a lower rate of reinfection.[13]

Despite the well-known benefits in terms of durability and performance, prosthetic valves are associated with a variable risk of thromboembolic and hemorrhagic events, particularly related to the need for anticoagulation in patients who, especially with higher age, exhibit varying degrees of independent risk profiles.[14]

To minimize the risk of thromboembolism and optimize the biocompatibility of implanted materials, various solutions have been proposed, such as homografts, allografts, and entirely biological conduits.

Homografts offer several advantages, rooted in their natural design and low incidence of thromboembolism and reinfection in cases of endocarditis.[3,12] Their inherent biological composition dramatically reduces hemolysis, whereas their frictionless nature allows unobstructed flow through physiological pathways. Notably, homografts exhibit enduring physical and geometrical characteristics, enabling permanent fixation and ensuring sustained functionality. For these instances, using an aortic homograft in cases of acute aortic valve endocarditis is linked to a low risk of recurring infection and good long-term survivals. However, the risk of reoperation due to structural valve deterioration becomes notably significant, particularly in younger patients, after a decade. Additionally, limitations in size and availability, as well as the tissue's natural tendency toward degeneration, restrict homograft use to a select group of patients.

To address these limitations, fully biological conduits have been developed to maximize biocompatibility and reduce thromboembolic events. The BioIntegral aortic valved conduit consists of a bovine pericardial conduit and a "stentless" porcine pericardial valve. Its unique construction, derived from 3 porcine aortic valves preserved through low-pressure glutaraldehyde fixation (<4 mm Hg), aims to balance flexibility, strength, and resistance to calcification. This pliability allows for adaptability in complex anatomies, making it suitable for challenging reconstructions of the mitro-aortic junction. Furthermore, by allowing surgeons to replace the entire ascending aorta, the "conduit" design eliminates the need for additional vascular prostheses.

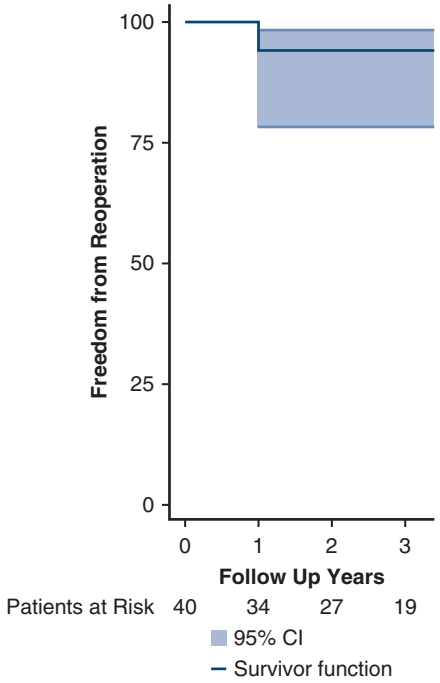

FIGURE 2. Kaplan–Meier analysis displaying freedom from reoperation at 0, 1, 2, and 3 years.

Recent studies have explored the effectiveness of fully biological prostheses in aortic root replacement. In 2013, Heinz and colleagues[15] investigated the use of the Freestyle aortic root prosthesis in 126 patients with aortic valve infective endocarditis. They observed 5- and 10-year survivals of 61.9% and 54.2%, respectively. Additionally, the combined end point of freedom from death, reoperation due to dysfunction, and recurrence of endocarditis was 56.3% at 5 years and 53.1% at 10 years.

A 2016 study by Wendt and colleagues[16] compared the hemodynamic performance of the BioValsalva and BioIntegral biological aortic-valved conduits in aortic root replacement. Their analysis of 55 implants, including approximately 20% of patients with acute type A aortic dissection, revealed no significant differences in mean pressure gradients or effective orifice areas between the 2 groups. Despite the high rates of concurrent procedures and emergency indications, both groups demonstrated a 30-day mortality of 7.3%.

In a study conducted in 2022, Botea and colleagues[9] assessed the results of using the BioIntegral Surgical Bioconduit in 91 patients. This treatment was specifically used in cases of endocarditis or complex disease of the aortic root. The authors reported a 30-day mortality rate of 8% and a structural valve deterioration rate of 13% at 1 year, with 2 reoperations.

In 2023, Salem and colleagues[17] reported the outcomes of surgical aortic root replacements with 2 distinct valved conduits: the LABCOR, a partially biological conduit, and BioIntegral. This retrospective study, involving 266 patients who underwent surgery from 2014 to 2020, placed a particular focus on those exhibiting preoperative endocarditis.

TABLE 4. Comparison between 30-day survivors and 30-day nonsurvivors

Variables	*P* value
Age	.060
Female sex	.547
EuroSCORE II	**<.001**
Hypertension	.716
Dyslipidemia	.096
Diabetes	.874
Chronic kidney disease	**<.001**
COPD	.431
CVD	**<.001**
Abscess	**<.001**
CPB time	**.027**
Crossclamp time	.830
ASCP time	**.014**
ICU stay	.208
Cardiac complications	.759
AF	**<.001**
Neurological complications	.700
Respiratory complications	**.003**
Transient dialysis	.258
Sepsis	**.001**
Postoperative bleeding requiring surgical revision	.586

Bold values are the statistically significant. *EuroSCORE*, European System for Cardiac Operative Risk Evaluation; *COPD*, chronic obstructive pulmonary disease; *CVD*, cerebrovascular disease; *CPB*, cardiopulmonary bypass; *ASCP*, antegrade selective cerebral perfusion; *ICU*, intensive care unit; *AF*, atrial fibrillation.

The study found that BioIntegral conduits were more often used in cases of prosthetic valve endocarditis, whereas LABCOR conduits were more commonly chosen for patients with ascending aortic aneurysms, Stanford type A aortic dissections, and degenerative aortic root pathology. It was observed that patients in whom BioIntegral conduits were implanted experienced higher complication rates, including pacemaker implantation, dialysis, and a higher 30-day mortality rate. Notably, postoperative echocardiographic findings did not show significant differences between the 2 types of conduits. Likewise, the survival analyses for both conduits were similar, with 1, 2, and 5-year survivals for the BioIntegral group of 81%, 74%, and 56%, respectively.

In 2020, Puehler and colleagues,[18] from the University of Kiel, Germany, reported the outcomes of 33 patients who received implantation of the BioIntegral conduit. Their study recorded a 30-day mortality rate of 33.0% (17). Ten of the 11 patients were affected by severe infective endocarditis, and they died approximately 9 days after surgery. The

team carried out a meticulous analysis, dividing their patients into 2 subgroups: those who survived within 30 days postsurgery and those who did not.

We decided to analyze our experience with this type of prosthesis, treating 46 patients affected by severe endocarditis involving the aortic root. Although this was a small population, our experience with the BioIntegral conduit showed an excellent long-term survival, with a 70.6% survival at the 5-year follow-up, along with excellent freedom from reoperation (81.9% at 60 months). Regarding 30-day mortality, only 4 of 46 patients (8.7%) died during the hospital stay. We believe that the BioIntegral conduit is a viable option in the treatment of complicated infective endocarditis involving the aortic root. Through a comprehensive analysis of patient outcomes, our findings reveal that these prostheses demonstrate promising outcomes in terms of biocompatibility, tissue integration, and long-term durability.

The entirely biological approach could eliminate the need for synthetic conduits and mechanical valves, offering significant benefits to patients who have a high risk of complications from anticoagulation therapy. Additionally, the fully biological structure of these prostheses may reduce the risk of recurrent infections and offer better adaptability to adjacent tissues damaged by the destructive infective process.

Although research into bioprostheses like the BioIntegral conduit demonstrates their potential to revolutionize the treatment of destructive endocarditis, long-term durability remains a crucial concern, particularly for younger patients.

Limitations

Although our study yields valuable findings and lays the groundwork for potential treatments, it does have significant limitations. Primarily, the small patient sample size may limit the scope of our results, and certain patient characteristics or rare complications may have been missed or underrepresented. On the other hand, to conclusively validate the BioIntegral conduit's effectiveness and safety for complex aortic root pathologies, larger and more varied patient population studies are needed to make proper comparisons with other non–fully biological valved grafts. This will help provide solid, reliable results that can better guide clinical practice.

CONCLUSIONS

Although the size of the patient sample treated with the BioIntegral prosthesis is limited, our results pointed toward a favorable long-term survival and minimal need for reoperation. The conduit appears to yield positive outcomes even in patients with redo operations who are often deemed more vulnerable and at an elevated risk of mortality. These initial results underscore the potential advantages of this treatment approach, emphasizing the need for further research with more extensive patient groups to thoroughly comprehend and consolidate these early observations.

Conflict of Interest Statement

The authors reported no conflicts of interest.

The *Journal* policy requires editors and reviewers to disclose conflicts of interest and to decline handling or reviewing manuscripts for which they may have a conflict of interest. The editors and reviewers of this article have no conflicts of interest.

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