Background. Dilatation of the pulmonary autograft is a major fear after the Ross procedure. We analyzed the results after reoperation for autograft dysfunction using a valve-sparing reimplantation technique (David procedure).

Methods. From 1995 to 2012, 645 Ross operations were performed, with 630 (98%) of these as freestanding root replacements (mean follow-up, 8.3 ± 4.6 years). Forty-nine autograft reoperations occurred in 46 patients (0.89%/patient-year). Between 2005 and 2013, reoperation using a David procedure was performed in 18 of 35 patients (52%) with autograft dilatation at a mean interval of 11 ± 3.2 years after the Ross operation.

Results. The mean age of 18 patients receiving a David procedure as reoperation was 49.8 ± 13.9 years; 83% were male. The 30-day reoperative mortality was zero. The mean vascular graft size used for reimplantation was 29.5 ± 1.7 mm. At a mean follow-up time of 3.2 ± 2.3 years (100% complete), all patients (18 of 18) were alive and in New York Heart Association functional class I. One patient (5%) needed valve replacement for recurrent aortic regurgitation 2.6 years after the David procedure. In the remaining patients (95%), freedom from aortic regurgitation of grade 2 or greater was 100% at 3 years (regurgitation grade <1, 14 of 17; 82%). Aortic valve gradients were clinically insignificant at 5.8 ± 2.1 mm Hg.

Conclusions. Performing a David procedure was successful in the vast majority of patients with dilatation of the pulmonary autograft after a Ross operation and revealed good function of the preserved autograft at midterm follow-up. Reoperations could be performed with low perioperative morbidity and mortality.

Material and Methods

Patients

From February 1995 to May 2012, 645 consecutive patients with a mean age of 42.3 ± 14.2 years (range, 1 to 68 years) underwent the Ross operation at our institution. Indications for surgery were aortic valve regurgitation in 186 patients (29%), stenosis in 203 patients (31%), mixed lesions in 215 patients (33%), or active endocarditis in 41 patients (7%) and patient’s preference to avoid anticoagulation, child-bearing potential in women, or a very active lifestyle. Three hundred seventy-three patients (58%) had bicuspid aortic valve morphology, and 209

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patients (32%) had ascending aortic aneurysm (diameter >5 cm). Contraindications included significantly reduced left ventricular function, greater than two-vessel coronary disease, known connective tissue disease or rheumatic disorder, and anatomic or structural anomalies of the pulmonary valve.

**Study Population**

Between 2005 and 2013, 35 reoperations were required as a result of a dilatation of the pulmonary autograft and consecutive aortic regurgitation at a mean interval of 11 ± 3.2 years after the Ross operation. In 18 of those 35 reoperations (52%), the autograft was preserved using a David procedure. Preoperative characteristics are shown in Table 1. The mean age at reoperation was 49.8 ± 13.9 years, and the mean follow-up was 3.2 ± 2.3 years (range, 0.3 to 8.5 years) and was 100% complete. This study was approved by our institution’s ethics committee, and informed consent was obtained from all patients or their families.

**Ross Operation**

In the majority of patients the freestanding root replacement technique was performed without (n = 224 [35%]; 1995–1998) or with (n = 406 [63%]; 1999–2012) autograft reinforcement, whereas 15 patients received a subcoronary transplant. Both techniques have been previously described in detail [4, 13, 14]. In the later series (1999–2012), a Dacron (polyethylene terephthalate fiber) strip was incorporated into the proximal suture line, and a second suture line fixed the aortic wall remnant to the autograft to provide reinforcement and prevent autograft dilatation [13].

<table>
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<tr>
<th>Table 1. Baseline Characteristics of Patients Receiving the David Procedure for Failure of Ross Operation</th>
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<tr>
<td><strong>Patient Characteristics</strong></td>
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<tr>
<td>Indication for initial Ross procedure</td>
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<tr>
<td>Insufficiency</td>
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<tr>
<td>Stenosis</td>
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<td>Mixed lesion</td>
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<td>Initial pulmonary autograft implantation technique</td>
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<td>Freestanding root</td>
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<tr>
<td>Grade of insufficiency at reoperation</td>
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<tr>
<td>0–1</td>
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<tr>
<td>2</td>
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<tr>
<td>3–4</td>
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<tr>
<td>Maximal neosinus diameter</td>
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<td>&lt;45 mm</td>
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<td>45–50 mm</td>
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<tr>
<td>&gt;50 mm</td>
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<tr>
<td>Bicuspid native aortic valve</td>
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<tr>
<td>Male</td>
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<tr>
<td>Age at reoperation (y, mean ± SD)</td>
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<td>Time since initial Ross procedure (y, mean ± SD)</td>
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SD = standard deviation.

**Indication for Reoperation on the Autograft**

Indications for autograft reoperation and patterns of autograft failure are presented in Table 2; these were classified according to the “Guidelines for Reporting Morbidity and Mortality After Cardiac Valvular Interventions” [28]. In patients with a failing autograft, indications for reoperation included neosinus dilatation of 50 mm or greater (regardless of the degree of autograft valve regurgitation) or an increase in root diameter of more than 5 mm/y (as per current guidelines for elective aortic root operations in individuals with Marfan syndrome or bicuspid aortic valve disease), and severe autograft regurgitation with symptoms of left ventricular dilatation or dysfunction [29]. Absolute contraindications to the David procedure were severe calcifications, an echocardiographically documented stenotic component of the autograft valve, and aortic cusps with large fenestrations.

**Reoperative Surgical Technique**

All reoperations were performed through repeated sternotomy using extracorporeal circulation, which was primarily established by cannulation of the distal ascending aorta and the right atrium. In patients with planned circulatory arrest, the right subclavian artery was used for arterial cannulation. When additional replacement of the aortic arch (n = 2) was performed, moderate hypothermic circulatory arrest (~28°C) with selective antegrade brain perfusion was initiated. After excision of the coronary ostia, the aortic sinuses were resected, leaving a remnant of 3 to 5 mm. The aortic root was mobilized to a level just below the aortic annulus. In male patients (15 of 18), a larger graft prosthesis of 30 mm was used to comply with the typically slightly larger annulus and to avoid procedure-related stenosis of the reconstructed autograft valve. The proximal anastomosis was performed using horizontal U-stitches placed circumferentially through the left ventricular outflow tract using Teflon (polytetrafluoroethylene) felt pledgets. The valve was then reimplanted into the prosthesis using a continuous suture line following the scalloped shape of the free margin of the

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<th>Table 2. Anatomic Patterns of Pulmonary Autograft Failure</th>
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<td><strong>Patient Characteristics</strong></td>
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<tr>
<td>Aortic dilatation (&gt;50 mm) at the initial Ross procedure</td>
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<tr>
<td>Root dilatation</td>
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<td>Ascending aneurysm</td>
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<td>Reinforcement at initial Ross procedure</td>
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<td>Annulus</td>
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<td>Sinotubular junction</td>
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<td>Indication for reoperation</td>
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<tr>
<td>Dilatation of neosinus of Valsalva</td>
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<td>Dilatation and autograft insufficiency</td>
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<td>Mechanism of autograft failure</td>
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<td>Dilatation of neosinus of Valsalva</td>
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<td>Dilatation of ascending aorta</td>
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<td>Cusp prolapse</td>
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native valve, allowing for correct cusp geometry and sufficient height of commissural resuspension within the prosthesis. The coronary ostia were implanted into the graft with a running suture [21]. The size of the vascular graft used for reimplantation of the aortic valve was 29.5 ± 1.7 mm. In 1 patient a frozen elephant trunk was used (JOTEC Inc, Hechingen, Germany). In most cases the neosinus of Valsalva was diluted without any evidence of fenestrations, calcifications, or tears of the valve leaflets. Additional autograft cusp repair was necessary in 7 patients and included central leaflet plication along the nodule of Arantius in relevant prolapses of the free margin, or free margin reinforcement by using a double-layer suture along the free margin [21]. Gore-Tex (W.L. Gore & Assoc, Flagstaff, AZ) sutures were used in all patients when cusp repair was indicated to avoid tearing and damage of the cusps. Intraoperative transesophageal echocardiography was used to assess satisfactory valve function. None of the patients intended to be treated with a David procedure required a prosthetic valve replacement.

Echocardiographic Data
All patients were prospectively monitored at discharge and annually at scheduled in-house visits. Echocardiographic evaluations were performed by the same experienced in-house physician in all cases.

Two-Dimensional Echocardiography
Autograft dimensions were measured at the following levels using the parasternal long-axis view of the aorta at end-diastole using the inner wall distances: (1) diameter of the aortoventricular junction (aortic annulus), (2) sinus of Valsalva, (3) the sinotubular junction, and (4) the proximal aorta, 2 cm above the sinotubular junction [30].

Continuous-Wave, Pulsed, and Color-Flow Doppler
Aortic insufficiency was graded according to Perry and colleagues [31]. Pulsed-wave Doppler and color-flow Doppler imaging were used to map the left ventricular outflow tract, including the ratio of jet height to left ventricular outflow tract height. Continuous Doppler imaging was applied to measure the deceleration slope and pressure half-time of the aortic insufficiency jet [31].

Statistical Analysis
Continuous data are presented as mean ± standard deviation or median (range) for nonparametric data. Survival was compared with age- and sex-matched general German population (www.destatis.de; Statistisches Bundesamt, Wiesbaden, Germany). Data were analyzed using JMP 8.0.1 software (SAS Institute Inc, Cary, NC).

Results
Early and Late Survival After Primary Ross Procedure
There were no intraoperative deaths, and 30-day mortality was 0.9% (6 of 645 patients). Overall cumulative survival at 15 years was 92.7% (95% confidence interval, 90.1% to 95.3%) and did not differ from that of the age- and sex-matched general German population (p = 0.261). Freedom from autograft reoperation at 12 years was 91.6% (95% confidence interval, 88.5% to 94.9%).

Mechanisms of Autograft Failure
Early autograft dysfunction within 1 year after the Ross procedure was owing to endocarditis (n = 8), rupture of the proximal autograft suture line (n = 1), covered rupture of the proximal autograft (n = 1), and development of aortic root pseudoaneurysm (n = 1; Fig 1). In the latter 3 of these 11 patients (27%), a valve-sparing procedure could be performed. Autograft dilatation was not a mechanism of early autograft dysfunction in our patient population.

Late autograft failure (>1 year postoperatively) required 38 reoperations in 35 patients (Fig 1). Three of these patients received simultaneous reoperation on the autograft and the pulmonary allograft. Late reoperations on the autograft can be divided into two subgroups.

In 15 of 38 late reoperations, there was no dilatation of the neosinus. The cause for autograft dysfunction with normal root geometry was endocarditis in 2 cases, and structural valve disease in 13 cases. A mechanical valve was implanted in a young male patient, and an older patient with predominant aortic valve stenosis and prior bypass surgery received a transapical aortic valve replacement. Valve dysfunction requiring second reoperation occurred in 2 patients, presenting at 13 and 19 months after initial isolated cusp repair, and was corrected with bioprosthetic valve replacement.

In the remaining 20 late reoperations, severe dilatation of neosinus, sinotubular junction, and the ascending aorta was prevalent as shown in Table 2. The autograft valve was replaced in 1 patient using a homograft and in 1 young patient by implanting a mechanical conduit. After gaining experience in valve-preserving techniques in the later series, the autograft was able to be salvaged using the David procedure in 18 patients.

The David Procedure
The David procedure was performed in 18 patients at a mean interval of 11 ± 3.2 years (median, 10.8 years; range, 3.5 to 15.6 years) after the initial Ross operation. In all patients, the initial pulmonary autograft had been implanted as a freestanding root. Autograft regurgitation was the indication for reoperation in all 18 patients (100%). Two patients (11%) showed associated neoaortic dilatation, and 2 patients (11%) had significant prolapse of one or more cusps. Noncoronary cusp prolapse and left coronary cusp prolapse were the most frequently observed disorders. Concomitant operative procedures are shown in Table 3. Mean hospital stay was 7.5 ± 1.7 days. The 30-day reoperative mortality for patients receiving the David procedure was zero. There were two reoperations for bleeding. Furthermore, no severe complications according to recent reporting guidelines were observed [28].
Echocardiographic Follow-Up Results

The mean follow-up time was 3.2 ± 2.3 years (median, 2.9 years; range, 0.3 to 8.5 years) and was 100% complete. No patients died during follow-up. At last follow-up, all patients were in New York Heart Association functional class I. The most-recent echocardiography showed 14 patients (78%) with regurgitation less than grade I, 3 patients (17%) with grade I, and 1 patient (6%) with grade IV, who required biologic valve replacement. In the subgroup of patients undergoing the David procedure with concomitant cusp repair (n = 7; 39%), there was no autograft regurgitation observed. Mean autograft valve gradient was 5.8 ± 2.1 mm Hg.

Comment

The Ross operation was introduced with the intent to provide an ideal solution for aortic valve disease, combining freedom from anticoagulation with optimal hemodynamic results [5, 6]. Autograft failure, as a result of dilatation or insufficiency, has emerged in a significant proportion of patients during long-term follow-up in some series [10, 19, 20]. Several studies confirmed preoperative aortic valve regurgitation and concomitant bicuspid aortic valve morphology being an independent risk factor for reoperation on the autograft, especially when using the root replacement technique [3, 5, 6]. However, patients presenting with an aortic regurgitation owing to annulus dilatation would likely receive valvesparing root surgery as the primary treatment strategy now and are not considered a candidate for a Ross operation anymore. In a recent report, Stulak and
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are shown to have significantly shorter life expectancies than the general population and have inferior outcomes compared with those undergoing the Ross operation with regard to survival [33]. Several recently published studies have already reported encouraging long-term results for valve-preserving techniques and repair strategies in the native aortic valve [13, 27]. Therefore, surgical judgment and careful patient selection are essential in deciding whether valve-sparing root replacement is the best option for any given patient. The reports on the David or Yacoub procedure after a complex operation such as the Ross procedure are very limited, and reported numbers of patients are low [23–26]. Many groups have used the remodeling technique to salvage a failing pulmonary autograft [20, 23, 26, 34]. The rationale of this procedure seems to be the reduced need for dissection of dense adhesions between the left and right ventricular outflow tract, avoidance of autograft valve to Dacron interaction, and ability to adjust specific sinus anatomy [26]. However, in our series the proximal aortic root could be mobilized off the pulmonary homograft by electric cautery. Observed adhesions were minor and not as tenacious as those observed after implantation of full root xenografts. Furthermore, Dacron prosthesis to autograft leaflet interaction could be minimized by means of re-creation of the sinus of Valsalva. We continue to perform the David procedure in patients with neosinus dilatation after a failed Ross procedure for additional annulus stabilization. Furthermore, it stabilizes the coaptation level under any functional condition of the cardiac cycle and makes concomitant cusp repair more reproducible [21]. Our current strategy of combining a David procedure with concomitant cusp repair, if indicated, is technically feasible. This is because of the interesting finding that the fragile pulmonary autograft valve leaflets remodel with time toward an aortic phenotype with development of noduli Arantii (Fig 2). Our studies suggest a more durable result when additional cusp repair is performed to a David procedure when compared with isolated cusp repair [27, 34]. Damage caused by potential leaflet contact with the Dacron graft used in the David procedure was not observed. Thus, the reimplantation technique does not appear to have a negative impact on the former pulmonary valve in the aortic position. When autograft dilatation has been monitored closely, the valve cusps themselves were rarely affected and retained their tri-leaflet architecture. This supports the idea that prompt intervention in patients with autograft dilatation of 50 mm or greater (as per current guidelines) avoids worsening autograft regurgitation and subsequent damage to the cusps [29]. In our series, no substantial dilatation occurred at the annular level. This may be because of our reinforcement technique of incorporating a Dacron

Fig 2. (A) Pulmonary valve with thin and pliable cusps at inspection before explantation and transfer into high-pressure system for a Ross operation. (B) Pulmonary autograft valve in aortic position with development of noduli Arantii (arrows) with a prominent free margin 10 years after the initial Ross operation.
strip into the proximal suture line of the pulmonary autograft valve to stabilize the annulus [5, 13]. However, a significant difference in need for reoperation in patients with or without annulus reinforcement as reported by other authors was not revealed in our series [13, 17]. During follow-up, freedom from significant aortic regurgitation was 95% in patients who had a David procedure irrespective of the need for associated cusp repair. Several reports describe disappointing results with solely leaflet shortening or plication [26, 34, 35]. This observation can be confirmed in the present study. Two patients underwent isolated cusp repair for autograft regurgitation and unfortunately exhibited recurrent valve regurgitation at 13 and 19 months after the first reoperation. These 2 patients subsequently required biologic valve replacement. We believe that cusp repair should only be used in combination with the David procedure to achieve satisfying mid- to long-term results as observed in the treatment of native aortic valve regurgitation [21].

Current Role of the Ross Operation in Light of Recently Published Guidelines

Although questionable durability and considerable perioperative risks have tempered enthusiasm for the Ross procedure with a downgrading in its indications for only a small subset of patients in recently published valvular heart disease guidelines, our reports suggest that the Ross operation should remain an alternative to conventional aortic valve replacement in selected patients [36]. In experienced centers, the Ross operation has a low perioperative risk and a low rate of reoperation, combined with a survival that is comparable to that of the general population [5]. No other valve replacement technique would yield this excellent performance with regard to survival and quality of life. The effect of the complexity of a procedure on outcome is highly correlated with the number of such procedures performed on a regular basis. This requires more engagement of the surgeon to develop skills to evaluate the applied surgical technique as well as the applied indication to establish the potential good outcome with this procedure.

Limitations

Although patients were prospectively monitored and valve function was serially assessed by echocardiography in most patients, the number of patients was relatively small, and the follow-up was relatively short.

Conclusions

Progressive neosinus dilatation remains a major limitation after the Ross operation. The data presented here indicate that the David procedure can be safely and effectively performed to salvage a dilated pulmonary autograft valve in a significant number of patients requiring autograft reoperation. At midterm, the David procedure has shown good results in these patients with no early or late morbidity. Owing to the limited number of patients receiving this treatment, longer follow-up and data consolidation from multiple centers is warranted to assess the durability of valve-sparing techniques for autograft salvage.

References