Heart disease (54%) followed by degenerative heart disease (22%). The indications for mitral valve replacement were stenosis (26%), mixed disease (21%) (regurgitation and stenosis), and previous prosthetic valve dysfunction (8%) (Figure 2).

Total 132 100%
Other 9 7%
Aneurysm Repair 3 2%
Pacemaker Insertion 6 5%
Aortic Valve/Annulus Repair 4 3%
Tricuspid Valve/Annulus Repair 46 35%
Stent Grafting 28 20%
Concomitant Grafting 28 20%
Concomitant Coronary Artery Bypass Grafting 17 12%

No. 435
Age Distribution at Implant

Introduction
The Carpentier-Edwards PERIMOUNT Mitral Pericardial Bioprosthesis, Model 6900, was introduced into clinical use in 1984, approved for U.S. commercial distribution in 1987, and is the only bioprosthesis approved for use in Europe.

From the Clinical Experience
CLINICAL COMMUNIQUE
16 YEAR RESULTS
Carpentier-Edwards PERIMOUNT Mitral Pericardial Bioprosthesis, Model 6900

APPENDIX 2: Statistical Methods

Nonsignificant estimates of adverse events were obtained by the method of Kaplan and Meier, with standard errors computed using Greenwood’s algorithm. Groups were compared using the log-rank test. The Cox proportional hazards model, giving the hazard ratio and associated confidence intervals, was used to assess the concomitant procedure (Figure 3).

Surgical Treatment
At the 435 patients, there were 241 patients undergoing coronary artery bypass grafting, 119 patients undergoing mitral valve replacement, and 75 patients undergoing combined procedures. The patients had undergone surgery at 77 centers. The median follow-up period of the 435 patients was 62 months (range, 0 to 185 months).

APPENDIX 5: Structural Valve Degeneration

In the current sub-study, data from the prosthesis performance were collected through review of patient records and reports from centers and companies. Of the 435 patients undergoing mitral valve replacement, 177 were reported to have undergone mitral valve replacement using only clinical evaluation (echocardiography, auscultation of murmurs, evaluation of NYHA class), rates vary widely in the literature. The patient’s valve continued to function well for many years; however, the more definitive diagnosis of SVD upon explant of the valve, which removes any subjective evaluation of valve failure.

In fact, a review of the literature shows that most published reports used only clinical evaluation (echocardiography, auscultation of murmurs, evaluation of NYHA class) to define valve dysfunction. In fact, a review of the literature shows that most published reports used only clinical evaluation (echocardiography, auscultation of murmurs, evaluation of NYHA class) to define valve dysfunction.

Parametric analysis of adverse events was performed using a constant hazard model, considering only events occurring 31 days or later after implant; confidence limits were computed using the log-rank test. The Cox proportional hazard model, considering only events occurring 31 days or later after implant; confidence limits were computed using the log-rank test.

APPENDIX 3: Functional Outcome

Descriptive statistics were summarized as the mean and standard deviation. Age and follow-up duration distributions were compared using the chi-square and Student’s t-tests. Parametric comparison of continuous data was performed using the Student’s t-test.

APPENDIX 1: Clinical Centers

<table>
<thead>
<tr>
<th>Center Name</th>
<th>No.</th>
<th>%</th>
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<tbody>
<tr>
<td>Toronto General Hospital</td>
<td>43</td>
<td>9%</td>
</tr>
<tr>
<td>Freeman Hospital, Newcastle-Upon Tyne, U.K.</td>
<td>76</td>
<td>17%</td>
</tr>
<tr>
<td>University Hospital, Gasthuisberg, Leuven, Belgium</td>
<td>36</td>
<td>8%</td>
</tr>
<tr>
<td>University Hospital, Uppsala, Sweden</td>
<td>46</td>
<td>11%</td>
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<tr>
<td>Walsgrave Hospital, Coventry, U.K.</td>
<td>90</td>
<td>21%</td>
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<tr>
<td>University of Toronto, Canada</td>
<td>18</td>
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<td>University of Toronto, Canada</td>
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Association (NYHA) classification. Preoperatively, 340 (78%) patients of the entire cohort (N=435) were in either Class III... – 17.2 years). Preoperative NYHA classification compared to the classification at last follow-up is presented (Figure 7).

At current follow-up, 104 (24%) patients were alive, 70% (N=157) alive at 10 years, 60% (N=139) alive at 15 years. Preoperative NYHA classification compared to the classification at last follow-up is presented (Figures 8, 9).

Most Common Etiology

- Rheumatic Heart Disease 54%
- Nonrheumatic 46%

Most Common Preoperative Diagnosis

- Congestive Heart Failure 16.9%
- Aortic Stenosis 14.8%
- Mitral Stenosis 11.4%

Summary of Actual Freedom from Explant Due to Structural Valve Deterioration - Cumulative Age Groups

- 0-5 years: Actuarial freedom at 16 years is 77.3%
- 6-10 years: Actuarial freedom at 16 years is 60%
- 11-15 years: Actuarial freedom at 16 years is 10%
- ≥16 years: Actuarial freedom at 16 years is 0%

Freedom From Valve-Related Expirations, Excluding Unknown

- 0-5 years: Actual freedom at 16 years is 88.0%
- 6-10 years: Actual freedom at 16 years is 54.7%
- 11-15 years: Actual freedom at 16 years is 29.6%
- ≥16 years: Actual freedom at 16 years is 2.8%

Freedom From Major Anticoagulant-Related Hemorrhage

- 0-5 years: Freedom from complication is 90%
- 6-10 years: Freedom from complication is 70%
- 11-15 years: Freedom from complication is 50%
- ≥16 years: Freedom from complication is 30%

Antithromboembolic Therapy

- 0-5 years: Freedom from anticoagulation-related hemorrhage is 90%
- 6-10 years: Freedom from anticoagulation-related hemorrhage is 70%
- 11-15 years: Freedom from anticoagulation-related hemorrhage is 50%
- ≥16 years: Freedom from anticoagulation-related hemorrhage is 30%

Surgical Procedures

- Sizes 27mm and 29mm were most frequently utilized.
- Sizes 31mm and 33mm were utilized to a lesser extent.

Results

- All patients with mitral valve disease had previous surgery.
- Some patients had atrial fibrillation preoperatively (N=293, 67%).
- Antithromboembolic therapy was reported for the 104 patients alive at last follow-up in Figure 6. Two patients were on two anticoagulants.
- Of the patients on anticoagulant therapy, 63% had rhythm disturbances.
- There were a total of 26 deaths classified as valve-related although the valve-relatedness was reported as "unknown" by the referring surgeon. Twenty other deaths were conservatively classified as valve-related although the valve-relatedness was reported as "unknown" by the referring surgeon. There were two other deaths that were considered to be valve-related because of lack of information to the contrary.

The mean age of the patients in this study was 60.7 years. The mean follow-up was 8.5 years. 2.2% of patients were lost to follow-up. The distribution of ages was 38% males and 62% females. New York Heart Association (NYHA) classification was compared to the classification at last follow-up.

Comparison of NYHA Functional Class: Preoperative and Last Follow-up

- Preoperatively, NYHA classification was III in 340 patients (78%).
- At last follow-up, NYHA classification was III in 333 patients (78%).
- NYHA classification at 5, 10, and 15 years was compared to the classification at last follow-up.

The mean ages of the patients were as follows:

- Overall Ages: 60.7 years
- Ages 0-5 years: 58 years
- Ages 6-10 years: 59 years
- Ages 11-15 years: 60 years
- Ages ≥16 years: 61 years

Details of the surgical procedures and antithromboembolic therapy are discussed in the literature. Therefore, analyses by overall ages (Figure 13) and by age segment (Figures 14-15) are presented.
The principal valve explants are defined in Figure 1. Valve explants are shown according to indicated etiology. These are represented in the bar charts on the left. The bar charts represent the fraction of each valve dysfunction etiology that led to explantation. The bar chart on the right represents the fraction of each valve dysfunction etiology that led to explantation.

Follow-Up
Follow-up data is shown in the chart on the right. The chart shows the number of patients who underwent valve replacement surgery. The chart also shows the percentage of patients who underwent valve replacement surgery that are still alive. The chart also shows the percentage of patients who underwent valve replacement surgery that have experienced a complication. The chart also shows the percentage of patients who underwent valve replacement surgery that have experienced a valve-related complication.

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Figure 5

Years Postoperative

15 16
14
12
11 13
10
9
7
5
4
2
0%

65 100% 97.3% 92.4%†

49 25 7

169
302
322
353
364

N=

A total of 80 valves were explanted during the postoperative period. Seventy-eight explants were valve related. Sixty-five explants were due to valve dysfunction, nine due to non-structural deterioration, four due to endocarditis.

Most Common Preoperative Diagnosis

60 100% 97.8% 88.7%†

3.0% ±

Actuarial freedom at 16 years is 47.1%

Preoperative I II III IV Explant Expired Explant Lost Missing Total

29 19 8 0 37 127 1 7 1 229

II0 2 0 0 3 6 0 0 0 1 1

Most Common Etiology

N=435

Figure 11

Freedom From Complication

10% 20% 30% 40%

Actuarial freedom at 16 years is 80.6%

Freedom From Valve-Related Expirations, Excluding Unknown

N=435

Actuarial freedom at 16 years is 89.4%

Freedom From Explant Due to Structural Valve Deterioration

N=435

Actuarial freedom at 16 years is 54.7%

Number of Patients 435

Comparison of NYHA Functional Class: Preoperative and Last Follow-up

New York Heart Association (NYHA) classification. Preoperatively, 340 (78%) patients of the entire cohort (N=435) were in either Class III (29.0%) or Class IV (17.2%) and 70% were in Class II. Preoperative NYHA classification compared to the classification at last follow-up is presented (Figure 7).

Functional improvement of all implant patients has been excellent. Preoperatively, 340 (78%) patients of the entire cohort (N=435) were in either Class III or IV; 66% showed functional improvement.

Postoperative Antithromboembolic Therapy

Aspirin/Anti-Platelet 24 23%

None 13 12%

Valve Size (mm)

70 years is 96.4

≥70 years is 96.4

60 years is 96.4

≥60 years is 96.4

Actuarial freedom at 16 years for patients < 60 years is 74.0%

Actuarial freedom at 16 years for patients 60 years is 47.1%

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Actuarial freedom at 16 years for patients ≥60 years is 29.6%
The most common etiology was rheumatic valve disease, with a total of 132 patients (100%). Other diagnoses included:

- Aneurysm Repair: 3 patients (2%
- Aortic Valve/Annulus Repair: 4 patients (3%)
- Pacemaker Insertion: 6 patients (5%)
- Tricuspid Valve/Annulus Repair: 46 patients (35%)
- Prophylactic Replacement: 1 patient (0.2%)
- Previous Prosthetic Valve Deterioration: 36 patients (8%)
- Mixed Disease: 93 patients (21%)
- Concomitant Procedure Number Percent
  - 0-10: 97 patients (22%)
  - 11-20: 48 patients (11%)
  - 21-30: 36 patients (8%)
  - 31-40: 61 patients (14%)
  - 41-50: 38 patients (9%)
  - 51-60: 54 patients (12%)
  - 61-70: 38 patients (9%)
  - 71-80: 18 patients (4%)

Of the 435 patients, 123 patients underwent 132 concomitant procedures. Coronary artery bypass grafting was the most frequently performed concomitant procedure (Figure 3).

APPENDIX 3: Structural Valve Deterioration

Deterioration (SVD) is defined as "any change in function (a decrease of one NYHA functional class or more) of an operated valve resulting from an intrinsic abnormality of the valve that causes stenosis or regurgitation."

According to the 1996 STS Guidelines, Structural Valve Failure is defined as "either an explant of a study valve due to regurgitation or stenosis; or a murmur associated with the study valve which had clinical consequences for the patient." Because of the relative subjectivity in the assessment of SVD and the variability in clinical presentations, morbidity and mortality rates vary widely. The more definitive diagnosis of SVD is obtained upon explant of the valve, which removes any subjective evaluation of valve failure.

APPENDIX 4: Statistical Methods

Descriptive statistics were summarized as the mean and standard error. Parametric analysis of adverse events was performed using a constant hazard model, considering only events occurring 31 days or later after implant; confidence limits were computed using the algorithms, as presented in Andersen et al., Statistical Models based on Counting Processes, Springer-Verlag 1993.
The most common etiology was rheumatic (80%).

Aneurysm Repair 3 (2%)
Aortic Valve/Annulus Repair 4 (3%)
Coronary Artery Bypass Graft 64 (48%)
Mixed Disease 93 (21%)
Regurgitation 193 (44%)
Stenosis 112 (26%)
Diagnosis Number Percent

Patients Percent

The Carpentier-Edwards PERIMOUNT Mitral Pericardial Bioprosthesis, Model 6900, was introduced into clinical use in 1984, approved for U.S. commercial distribution in 1985, and received the CE Mark marking in the European Union. The data represented below is a summary of the clinical experience of seven centers in Europe and Canada.

APPENDIX 1: Clinical Centers

Introduction

The primary purpose of this study was to assess the durability of the Carpentier-Edwards PERIMOUNT Mitral Pericardial Bioprosthesis, Model 6900, used for mitral valve replacement in a high-risk surgical population.

Materials and Methods

A total of 435 patients were implanted between January 1984 and December 1989. The majority, 333 (77%) patients underwent isolated mitral valve replacement (MVR), and 102 (23%) underwent concomitant procedures. Coronary artery bypass grafting was the most frequently performed concomitant procedure. Sixteen patients (6%) presented with a history of congestive heart failure.

The Carpentier-Edwards PERIMOUNT Mitral Pericardial Bioprosthesis, Model 6900, was introduced into clinical use in 1984, approved for U.S. commercial distribution in 1985, and received the CE Mark marking in the European Union. The data represented below is a summary of the clinical experience of seven centers in Europe and Canada.

APPENDIX 1: Clinical Centers

APPENDIX 2: Statistical Methods

APPENDIX 3: Structural Valve Deterioration

Deterioration (SVD) is defined as "any change in function (a decrease of one NYHA functional class or more) of an operated valve resulting from an intrinsic abnormality of the valve that causes stenosis or regurgitation."

According to the 1996 STS Guidelines, Structural Valve Deterioration was defined as "either an explant of a study valve due to regurgitation or stenosis; or a murmur associated with the study valve which had clinical consequences for the patient." At that time, the FDA's guideline was to report bioprosthetic valve performance in terms of "valve dysfunction" defined as "either an explant of a study valve due to regurgitation or stenosis; or a murmur associated with the study valve which had clinical consequences for the patient." When the PERIMOUNT bioprosthesis was first introduced into clinical studies in 1981, the STS Guidelines (first published in 1988) on reporting morbidity and mortality after cardiac valvular operations did not exist.

These were the guidelines originally used to define valve dysfunction. When the PERIMOUNT bioprosthesis was first introduced into clinical studies in 1981, the STS Guidelines (first published in 1988) on reporting morbidity and mortality after cardiac valvular operations did not exist.

The essential requirements referred to in Article 3 of the Medical Device Directive 93/42/EEC bear the CE marking of conformity. Edwards Lifesciences devices placed on the European market meet the essential requirements referred to in Article 3 of the Medical Device Directive 93/42/EEC.