INTRODUCTION: Aim of the study was to evaluate the hemodynamic and clinical performance of the Mosaic bioprosthesis in the aortic position.

PATIENTS AND METHODS: The Mosaic bioprosthesis is a stented porcine heart valve for implantation in the aortic and mitral position, which combines zero pressure and root pressure fixation with glutaraldehyde, antimineralization treatment with alpha amino oleic acid (AOA) and a low profile stent, to optimize hemodynamic function and to minimize mechanical wear and thus to achieve longer tissue durability. Included in a multicenter study, 100 patients (49 females) underwent isolated aortic valve replacement with the Mosaic bioprosthesis between February 1994 and May 1999. Average age at implant was 73.4 +/- 7.3 years (range 31.3-86.8 years). Preoperative and operative clinical data are shown in Tables 1 and 2. Patients were followed-up within the first 30 postoperative days, after six months and at annual intervals, including transthoracic echocardiography and documentation of any adverse events. Mean follow-up was 3.8 years (range 0.1-7.1 years), total 383.1 patient-years. Follow-up is 100% complete. RESULTS: One year after implantation of the bioprosthesis, mean systolic pressure gradient was 15.3 +/- 6.7 mmHg (21), 14.5 +/- 5.7 mmHg (23), 12.7 +/- 4.1 mmHg (25) and 13.0 +/- 4.8 mmHg (27); effective orifice area (EOA) was 1.4 +/- 0.4 cm² (21), 1.7 +/- 0.4 cm² (23), 1.8 +/- 0.4 cm² (25).
cm2 (25) and 2.6 +/- 0.4 cm2 (27) (Table 3). One year postoperative, nine patients (10.8%) showed mild aortic regurgitation and one patient (1.2%) moderate. Left ventricular mass index decreased significantly for all sizes within the first postoperative year from 159.7 +/- 56.8 g/m2 to 137.3 +/- 40.8 g/m2. Separating the patients with regard to valve size, only the 21-group (154.1 +/- 51.2 g/m2 to 129.1 +/- 34.6 g/m2) and the 27-group (237.7 +/- 59.2 g/m2 to 146.7 +/- 20.6 g/m2) showed significant results. Freedom from event rates at seven years were 96.8 +/- 1.8% for thromboembolic events, 97.2 +/- 2.0% for thrombosed bioprosthesis, 96.6 +/- 2.6% for structural valve deterioration, 98.2% +/- 1.8% for nonstructural dysfunction, 95.9% +/- 2.0% for antithromboembolic hemorrhage, 98.9 +/- 1.1% for endocarditis and 93.9 +/- 3.2% for reoperation and explant (see Table 4). Early mortality (within 30 days) was 3.0%; late mortality was 4.6%/patient-year, including a valve-related mortality of 0.6%/patient-year. Of the patients, 96.5% showed an improvement of at least one NYHA class when comparing preoperative and one year status. DISCUSSION: The hemodynamic performance and the frequency of adverse events of the Mosaic bioprosthesis in the aortic position were very satisfactory within the first seven postoperative years with excellent results, comparable to studies about other established bioprostheses and similar to the findings in other Mosaic series. Only the number of cases of antithromboembolic hemorrhage was noticeably high. One reason might be the high percentage of patients under continuous anti-coagulant therapy: Six months postoperative, still 52.2% of the patients received phenprocoumon, 6.7% acetylsalicylic acid. Concerning hemodynamics, patient-prosthesis mismatch appeared to be a common problem, especially in small valve sizes. Separating the sample in groups with EOA index 0.75 cm2/m2 after one year, 51.6% in the 21-group had an EOA index < or = 0.75 cm2/m2, whereas it was 19.4% (23), 18.8% (25) and 0% (27) in the larger size groups. Generally, further data have to be collected to determine durability of the biological tissue, as the critical period has just started with the seventh year of the clinical trial. CONCLUSION: The Mosaic bioprosthesis proved to be a reliable and well-functioning device for aortic valve replacement, especially in larger sizes.