BACKGROUND
The St. Jude Medical Trifecta valve is a novel aortic biological prosthesis that incorporates several design features, including a true supra-annular sewing cuff, a stent design that maximizes valve hemodynamics while minimizing leaflet stresses and an ethanol-based anti-calcification technology. This study establishes safety, early clinical and hemodynamic performance of the Trifecta valve.

METHODS
The Trifecta bioprosthesis was implanted in 1,014 eligible patients between 2007 and 2009 at 31 centers. The mean age of the population was 72.5 ± 9.0 years of which 650 [64.1%] were males and 364 [35.9%] were females. Eighty-two [8.1%] subjects had undergone previous open heart surgery. Indications for aortic valve replacement surgery included stenosis in 556 [54.8%] patients, regurgitation in 61 [6.0%] patients and mixed pathology in 397 [39.2%] patients.

RESULTS
The overall follow-up included 844.3 late patient-years. Early (≤ 30 day) mortality occurred in 18 [1.8%] patients and there were 23 late (≥ 31 days) deaths yielding a linearized mortality rate of 2.72% per late patient-year. There were 27 early thromboembolic events, including 8 [0.8%] strokes, 17 [1.7%] reversible neurologic events and 2 [0.2%] systemic embolic events. There were no instances of early valve thrombosis, endocarditis or clinically significant hemolysis. There were 16 late thromboembolic events (linearized rate of 1.90% per year of follow-up), including 4 strokes and 12 reversible neurologic events. In total, there were 5 late valve explants, including 1 structural deterioration and 4 prosthetic valve endocarditis cases. Overall, freedom from valve explant was 99.4% at 2 years. Figure 1 shows the average mean gradients collected on patients by valve size at 1 year.

RESULTS IN CONTEXT
Based on the results of the current study, the Trifecta valve represents significant progress in the development of a stented bioprosthesis with near physiologic hemodynamics. The nearly cylindrical opening of the prosthesis on systole provides gradients and effective
orifice areas that surpass any other available stented aortic prosthesis and approach those of stentless prostheses.

- The favorable hemodynamics led to an incidence of severe prosthesis-patient mismatch (PPM) that was uniquely low for the Trifecta valve. Overall freedom from severe PPM at 1 year was 94.8%.

- Among patients receiving 19 mm, 21 mm and 23 mm prostheses, at 1 year, the mean indexed effective orifice area was 0.85 cm²/m², 0.90 cm²/m² and 0.91 cm²/m², respectively. Severe mismatch with an effective orifice area of less than 0.65 cm²/m² was found in only 5.5% of patients at one year.

- The presence of severe PPM has been shown in several studies to lead to significantly poorer long-term survival in a variety of patient groups. In series with older generation prostheses and varying definitions of mismatch have been reported up to 51%.

- In the current study, the Trifecta valve had an extremely low rate of paravalvular leak despite having a highly efficient low-profile sewing ring, indicative of ease of implantability. There was also minimal valvular regurgitation even in larger sizes, a problem more common in previous generation surgical pericardial valves.

CONCLUSIONS

In summary, the St. Jude Medical Trifecta valve is a unique pericardial bioprosthesis with design elements that provide excellent hemodynamic performance while providing ease of implantation. Long-term follow-up continues in order to confirm the promising results of this innovative bioprosthesis.

REFERENCE