Safety and feasibility of a cardiac support device


Abstract
The Cardiac Support Device (CSD), a preformed-knitted polyester device surgically placed over the cardiac ventricles, prevents left ventricular (LV) remodeling and improves LV ejection fraction (EF) in dogs with heart failure (HF). This study was designed to examine the safety of the CSD in patients with advanced HF. As of December 31, 1999, the CSD was implanted into 22 patients with myocardial disease. Ten patients had concomitant mitral valve repair, two patients had valve replacement (one patient aortic and one patient mitral), one patient had LV assist device (LVAD) placement, and eight patients received only the CSD. The CSD was placed while on bypass with the heart beating, attached to the epicardium groove, and tailored anteriorly to snugly fit the ventricles. There were no intraoperative deaths or complications. Two patients died early from non-CSD-related causes 4 and 23 days postoperatively; one late death occurred. Of the remaining 19 patients, none had any CSD-related adverse events during an average 3.5 ± 0.4 month follow-up. All patients had completed 3-month follow-up. No patients had evidence of constrictive and/or restrictive physiology. Mitral valve regurgitation (MVR) improved in all patients. [table: see text] Initial findings indicate that the CSD is safe and improves heart failure symptoms and LV function. Additional studies and longer follow-up are needed to confirm these results.

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