The Cardica C-Port System: Clinical and angiographic evaluation of a new device for automated, compliant distal anastomoses in coronary artery bypass grafting surgery—A multicenter prospective clinical trial

Klaus E. Matschke, MD,[a] Jan F. Gummert, MD,[b] Stefanos Demertzis, MD,[c] Utz Kappert, MD,[a] Marcel B. Anssar, MD,[d] Francesco Siclari, MD,[c] Volkmar Falk, MD,[b] Edwin L. Alderman, MD,[e] Christian Detter, MD,[f] Hermann Reichenspurner, MD,[f] and Wolfgang Harringer, MD[d]

Objectives: The C-Port System (Cardica, Inc, Redwood City, Calif) integrates in one tool all functions necessary to enable rapid automated distal coronary anastomoses. The goal of this prospective, nonrandomized, and multicenter study is to determine the safety and efficacy of this novel anastomotic system.
Methods: Five centers enrolled 133 patients awaiting elective coronary artery bypass grafting surgery. Outcome variables were intraoperative device performance, incidence of device-related adverse events, predischarge and 6-month angiographic graft patency, and 12-month clinical outcome. Independent core laboratories performed qualitative and quantitative angiographic and computed tomographic assessments.
Results: The C-Port was used to perform a vein-to-coronary anastomosis in 130 patients. Intraoperative conversion to a hand-sewn anastomosis was necessary in 11 patients because of inadequate target site preparation, inappropriate target vessel selection, or both. Inadequate blood flow related to poor runoff required conversion in 3 additional patients. Three patients died before discharge of causes unrelated to the device. At discharge, 113 patients had a C-Port implant in place, and 104 C-Port anastomoses were studied by means of angiography, resulting in 100 FitzGibbon A, 3 FitzGibbon B, and 1 FitzGibbon 0 classifications. At 6 months, one additional patient died of a device-unrelated cause, and 98 patients were evaluated by means of angiography (n _ 89). Overall patency (FitzGibbon A) was 92.1%. Three C-Port anastomoses were rated FitzGibbon B, and 4 were rated FitzGibbon 0. At 12 months, 107 (98.2%) of 109 alive patients were followed up, without any reports of device-related major adverse cardiac events.
Conclusions: The C-Port System allows for a rapid, reliable, and compliant distal anastomosis and yields favorable 6-month angiographic and 12-month clinical results when compared with published studies.