Sutureless Proximal Anastomosis Using the PAS-Port System: Six-Month Patency and Five-Year Follow-Up in "All-Comers"

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Background. **The PAS-Port system (Cardica, Inc, Redwood City, CA) was used routinely for patients undergoing coronary surgery with at least one venous graft. Graft patency and clinical results were evaluated, respectively, at 6 months and 5 years after surgery.**

Methods. **A total of 100 patients (82 males, 18 females; mean age 68.9 ± 12 years) underwent coronary bypass surgery with at least one PAS-Port anastomosis (total number of PAS-Port implants: n = 117). At 6 months after surgery all patients were followed up clinically and 86 patients with 101 PAS-Port implants underwent either a multidetector computed tomographic scan or coronary angiography. Actuarial freedom from MACCE (major adverse cardiac and cerebrovascular events) was assessed at 5 years after surgery.**

Results. **Six-month PAS-Port patency was 88%. The inner diameter of the graft at the implant site (measured in 26 patients) did not reveal any pathologic narrowing (mean inner diameter 3.1 ± 0.6 mm). At 5 years, freedom from overall MACCE was 79% ± 5% and freedom from PAS-Port target vessel revascularization was 94% ± 6%.**

Conclusions. **The routine use of PAS-Port was associated with good vein graft patency at 6 months and a low incidence of MACCE at 5 years after surgery. No evidence of implant-related graft stenosis was detected.**

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The use of automated devices for the construction of the anastomosis between a saphenous vein graft (SVG) and the ascending aorta ("proximal anastomosis") could guarantee a geometrically standardized anastomosis, save time, and decrease the incidence of complications related to aortic site clamping, especially in the setting of off-pump coronary surgery (OPCAB).

The PAS-Port system (Cardica Inc, Redwood City, CA) (Fig 1) allows for the rapid connection of a SVG with the aorta by a stainless-steel implant without the need for aortic clamping. The device follows the "all-in-one" concept; ie, it performs all steps necessary for the anastomosis (aortotomy included) by the simple turning of an actuation knob. After a promising initial experience [1], we adopted the PAS-Port system in our clinical practice. This communication summarizes our long-term results.

Patients and Methods

Data was collected prospectively after the introduction into clinical practice of a CE-marked and later FDA-cleared product. This study was approved by the Institutional Review Board.

Between April 2004 and November 2007 a total of 100 patients, 82 males and 18 females (mean age 68.9 ± 12 years) underwent coronary artery bypass grafting with at least one PAS-Port anastomosis. Patient selection was initially based on patient history, findings, and risk factors for ascending aortic atherosclerosis and, following good initial results, enrollment became consecutive. All surgical procedures were performed by one surgeon.

All coronaries with hemodynamically significant stenosis and a diameter of at least 1.5 mm were considered targets. It was preferred to revascularize the right and left coronary system separately, using single or sequential SVG and (or) arterial grafts. The use of additional arterial grafts (besides the left internal mammary artery) was generally favored but limited to target vessels with critical stenoses (>80%) and to elective patients younger than 70 years. There was no target vessel selection with regard to the use of PAS-Port as the inflow of all SVG originated from one or more PAS-Port implants. In case of multiple SVG multiple PAS-Port systems were used. Alternatively, for vein segments with dimensions not compatible with the device's specifications (4 to 6 mm outer diameter), T grafts were constructed originating from one PAS-Port graft.

On-pump surgery was performed in light hypothermia (32°C) using standard extracorporeal circulation. In off-pump or assisted beating heart surgery a disposable suction stabilizer was used. Patients were fully heparinized and then reversed with protamine (1:1 ratio).

Intraoperative documentation included measurement of graft flow and its characteristics (mean flow, pulsatility

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Abbreviations and Acronyms

ASA = acetylsalicylic acid
CABG = coronary artery bypass grafting
CS = Canadian cardiovascular society
Cx = circumflex artery
ECC = extracorporeal circulation
EF = ejection fraction
IMA = internal mammary artery
LAD = left anterior descending artery
LIMA = left internal mammary artery
MACCE = major adverse cardiac and cerebrovascular events
MDCT = multidetector computed tomographic scan
ONCAB = on-pump coronary artery bypass
OPCAB = off-pump coronary artery bypass
PI = pulsatility index
RCA = right coronary artery
RIMA = right internal mammary artery
RA = radial artery
SD = standard deviation
SVG = saphenous vein graft
TTF = transit time flow

index, proportion of diastolic and backflow [2]) by means of the transit time flow technique (MediStim, Oslo, Norway). The need for graft revisions, additional stitches, or technical complications related to the PAS-Port implant, were documented.

Antiplatelet therapy was based on acetylsalicylic acid (100 mg/d). Acetylsalicylic acid treatment was not interrupted for surgery and continued lifelong thereafter. The use of PAS-Port did not influence antiplatelet treatment. In patients with T grafts and (or) sequential arterial grafts and (or) specific surgical findings (extensively calcified vessels, endarterectomy), clopidogrel (Plavix; Sanofi/Bristol-Myers Squibb, Meyrin/GE, Switzerland) was added empirically (75 mg/d, starting 24 hours after surgery without a loading dose).

Patency was evaluated at 6 months after surgery by means of either coronary angiography or multidetector computed tomographic scan (MDCT). The MDCT was performed initially with a 16-slice (patients 1 through 40; Sensation 16, Siemens Medical Solutions, Forchheim, Germany; or Brilliance 16, Royal Philips Electronics, Best, the Netherlands) and then a 64-slice MDCT (LightSpeed VCT; GE Healthcare, Waukesha, WI) according to standard protocols. All patients signed a written informed consent prior to MDCT or coronary angiography.

Grafts were evaluated for patency and pathologic focal narrowing. Patients evaluated by MDCT showing evidence of graft occlusion or significant stenosis (greater than 60% of the graft diameter) were referred for further cardiologic evaluation.

Screening for MACCE (major adverse cardiac and cerebrovascular events) was continuous and prospective. At a cutoff date (March 2010) additional screening was performed by means of hospital database queries and standardized telephone interviews of all patients. In cases of identified or suspected MACCE the primary care physician was interviewed and copies of the respective charts and findings were requested and reviewed. The MACCE were defined as any of the following after discharge: death, myocardial infarction, percutaneous transluminal coronary angioplasty of any vessel, PAS-Port target vessel, or graft revascularization, or any stroke.

Logistic EuroSCORE (European system for cardiac operative risk evaluation; [log ES]) was used for risk stratification and risk-adjustment purposes [3]. Means are expressed ± standard deviation. The Student t test was used for continuous normally distributed data and (or) responses and the χ^2 test for categoric responses. The predictive value of categoric variables on graft patency was tested by means of binary logistic regression. The MACCE were analyzed as time-related events by means of univariate product-limit (Kaplan-Meier) survival esti-

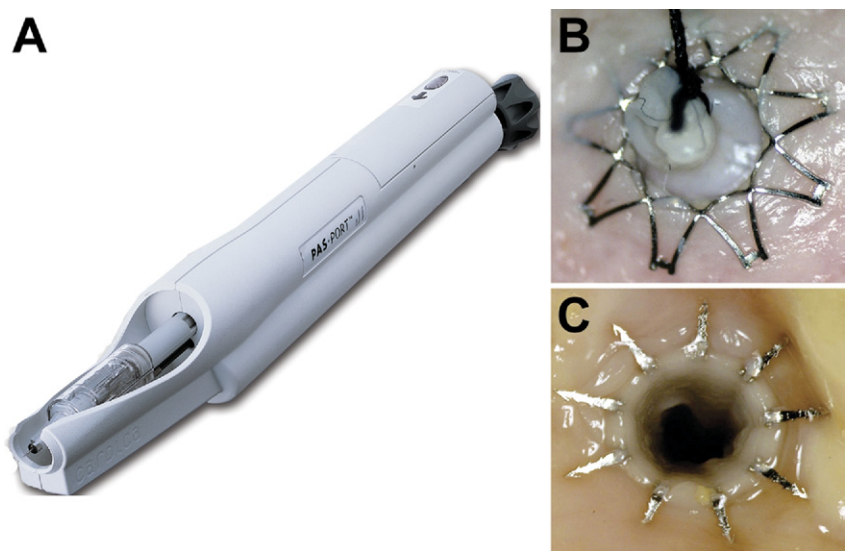

Fig 1. PAS-Port tool and implant. (A) The PAS-Port tool. At its tip the rotatory knife and the auger tip for the capture of the aortic wall plug. (B) The PAS-Port implant (external view). (C) The PAS-Port implant (internal view).