



**Australian Government**  
**Department of Health and Ageing**



# Horizon Scanning Technology Prioritising Summary

## Totally endoscopic coronary artery bypass surgery

February 2007

(Updated February 2008 and February 2009)



**Australian  
Safety  
and Efficacy  
Register  
of New  
Interventional  
Procedures -  
Surgical**



**Royal Australasian  
College of Surgeons**

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The production of this Horizon scanning prioritising summary was overseen by the Health Policy Advisory Committee on Technology (HealthPACT), a sub-committee of the Medical Services Advisory Committee (MSAC). HealthPACT comprises representatives from health departments in all states and territories, the Australia and New Zealand governments; MSAC and ASERNIP-S. The Australian Health Ministers' Advisory Council (AHMAC) supports HealthPACT through funding.

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# PRIORITISING SUMMARY

**REGISTER ID:** S000019

**NAME OF TECHNOLOGY:** TOTALLY ENDOSCOPIC CORONARY ARTERY BYPASS SURGERY (DA VINCI SYSTEM)

**PURPOSE AND TARGET GROUP:** PATIENTS SUFFERING FROM CORONARY ARTERY DISEASE

**STAGE OF DEVELOPMENT (IN AUSTRALIA):**

- |   |   |
|---|---|
| <input type="checkbox"/> Yet to emerge      | <input checked="" type="checkbox"/> Established   |
| <input type="checkbox"/> Experimental       | <input type="checkbox"/> Established <i>but</i> changed indication or modification of technique |
| <input type="checkbox"/> Investigational    | <input type="checkbox"/> Should be taken out of use   |
| <input type="checkbox"/> Nearly established |   |

**AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL**

- |   |             |     |
|---|-------------|-----|
| <input checked="" type="checkbox"/> Yes | ARTG number | N/A |
| <input type="checkbox"/> No             |             |     |
| <input type="checkbox"/> Not applicable |             |     |

**INTERNATIONAL UTILISATION:**

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
Austria		✓	
Belgium		✓	
Canada		✓	
Denmark		✓	
France		✓	
Germany		✓	
India		✓	
Italy		✓	
Japan		✓	
Netherlands		✓	
Romania		✓	
Saudi Arabia		✓	
Singapore		✓	
Sweden		✓	
Switzerland		✓	
United Kingdom		✓	
United States		✓	

**IMPACT SUMMARY:**

Intuitive Surgical Inc. (United States) provides the da Vinci surgical system with the aim of providing robotically-assisted minimally invasive procedures in various medical disciplines.

This technology is available in specialist medical centres as an alternative to open cardiac bypass surgery for patients suffering from coronary artery disease.

## **BACKGROUND**

Coronary artery disease occurs when the coronary arteries are affected by build-up of atheromatous plaque within the walls of the vessels. The progressive build-up of plaque will eventually result in substantial stenosis/narrowing of the coronary artery (atherosclerosis) therefore leading to insufficient blood flow to the myocardium. As the stenosis progresses, patients will experience angina and eventually heart attack if the plaque completely blocks the flow of blood.

Coronary artery bypass grafting (CABG) is a procedure performed to relieve angina and reduce the risk of death due to coronary artery disease. This procedure basically involves the grafting of arteries or veins harvested from another part of the patient's body to bypass the section of the artery which is affected by stenosis in order to restore optimum blood supply to the myocardium. Traditionally, CABG is performed through a sternotomy, an approach that provides optimal access to all cardiac structures and the great vessels. For many years, cardiopulmonary bypass (CPB) and cardioplegic arrest have been regarded as necessary to provide a bloodless and motionless operating site which enables the surgeon to perform the procedure in comfort and safety. As technology improved, minimally invasive CABG was developed to perform the entire anastomoses endoscopically and to avoid CPB. One of the earlier methods developed was minimally invasive direct vision coronary artery bypass (MIDCAB). This procedure combines the advantages of limited surgical access with the benefits of off-pump surgery. However, MIDCAB is limited to revascularisation of a maximum of two target vessels (Dogan et al. 2002) and research has indicated that the MIDCAB procedure has the drawback of difficult internal mammary artery (IMA) harvest and intercostal pain during the immediate post-operative period (Katz et al. 2006). Recently, the development of robotically enhanced telemanipulation has further advanced minimally invasive CABG, therefore allowing surgeons to perform totally endoscopic coronary artery bypass (TECAB) procedures.

The device utilised to perform TECAB is the da Vinci telemanipulation system (Intuitive Surgical, California). The da Vinci system is a master-slave telemanipulation system which consists of a remote console where the operating surgeon (master) directs the robotic surgical arms (slave) via a telerobotic videoscopic link (Figure 1).

**Figure 1: The da Vinci telemanipulation system**



© 2004 Intuitive Surgical

The system is capable of providing high resolution 3D videoscopic images and allows remote, tremor-free and scaled control of endoscopic surgical instruments with 6 degrees of freedom (Mohr et al. 2001). The master console enables remote control of the endoscopic instruments mounted on a surgical cart with three (or four) robotic arms. The middle arm carries a stereo endoscope, while the left and right arms serve as endo-thoracic end effectors for remote tissue manipulation using instruments that resemble the human wrist. The video image from the stereo endoscope is relayed to the master console as a 10x magnified 3D image which provides the surgeon with optimal visualisation of the surgical field (Dogan et al. 2002).

### **CLINICAL NEED AND BURDEN OF DISEASE**

Coronary artery disease (a.k.a. coronary heart disease) is the most common form of heart disease in Australia. Based on the 2004-2005 National Health Survey, 1.7% of Australians surveyed admitted to having manifestations of coronary artery disease. This corresponds to approximately 334,500 Australians affected by this disease. The Australian Institute of Health and Welfare reports that in 2003, there were approximately 49,800 coronary artery disease events in Australia among 40 to 90 year olds. Less than 50% of these events were fatal (21,480 fatalities) and 86% of these deaths occurred outside of a hospital (AIHW 2006).

Coronary artery disease presents a substantial burden to the healthcare system as it accounts for 36% of all hospitalisations for cardiovascular disease in 2003 – 2004 (164,226 hospitalisations for coronary artery disease). In addition to this, coronary artery disease has been determined as the largest single cause of death in Australia in 2004, accounting for 24,576 deaths, which equates to 19% of all deaths, and 51% of cardiovascular deaths (AIHW 2006).

### **DIFFUSION**

The da Vinci system is available in the United States, Europe, Asia and various other parts of the world. The Food and Drug Administration (FDA) in the United States cleared the da Vinci system in 2000 for general laparoscopic procedures. Following this, the system was approved for prostatectomy, non-cardiac chest procedures and procedures involving surgical incisions into the heart (mitral valve repair). In 2004, the FDA expanded the application of the da Vinci system to CABG. In Europe the da Vinci system has full regulatory clearance and is entitled to affix the CE mark to the system. In Australia, the da Vinci surgical robotic system is listed on the Therapeutic Goods Administration (TGA) Australian Register of Therapeutic Goods (ARTG) (Class IIb) and is distributed in Australia by Device Technologies Australia, P/L.

## COMPARATORS

At the time of writing, there are no other robotic telemanipulator systems that are comparable to the da Vinci system. Previously, Computer Motion Inc. (California) manufactured the Zeus Robotic Surgical System which was similar to the da Vinci system. However, this system is no longer marketed and Computer Motion was bought by Intuitive Surgical in 2003 (FDA 2005). The comparators to robotically assisted TECAB are:

- Conventional CABG via open thoracotomy
- MIDCAB
- OPCAB (Off-pump coronary artery bypass)

## SAFETY AND EFFECTIVENESS ISSUES

The prospective FDA-sanctioned multicenter trial conducted by Argenziano et al. (2006) investigated the safety and efficacy of *arrested/non-beating* heart, *single-vessel* TECAB utilising the da Vinci system in 98 patients requiring left anterior descending (LAD) coronary artery revascularisation. The left internal mammary artery (LIMA) was harvested as the graft vessel. A total of 13 patients were excluded intraoperatively due to inability to establish effective peripheral cannulation, deep intramyocardial coronary targets that could not be visualised epicardially and dense pleuropericardial adhesions. Of the 85 patients undergoing TECAB, 5 patients (6%) required conversion to other techniques. One patient (1%) required reintervention of the target vessel on the first post-operative day due to graft occlusion. At 3-months follow-up angiography (n = 76), anastomotic occlusion was observed in 2 patients while significant anastomotic stenosis ( $\geq 50\%$  occlusion) was noted in 4 patients. Overall, 7/75 (9.3%) patients who underwent TECAB had either graft vessel reintervention or angiographic confirmation of graft failure; this corresponds to a freedom from graft failure of 91%. The total operative time was  $353 \pm 89$  minutes (mean  $\pm$  SD) (range: 200 – 600 minutes) and the length of hospitalisation was  $5.1 \pm 3.4$  days (range: 1.2 – 25.5 days). A total of 26 patients (31%) required blood products perioperatively, this transfusion rate was higher than expected and may reflect the longer surgical times in some patients. No deaths were reported throughout the trial. However, the 4 cases of reinterventions and one case of perioperative myocardial infarction results in 5 major adverse cardiac events in 85 patients (5.9%). In addition, there were 5 cases (5.9%) of groin infections as a result of the procedure (Argenziano et al. 2006).

In another *arrested* heart TECAB case series study involving 45 patients with single- or double-vessel disease (37 single bypasses, 8 double bypasses), Dogan et al. (2002) reported that 11 patients (24.4%) required intraoperative conversion to either left-sided minithoracotomy (n = 8) or median sternotomy (n = 3). The first 22 TECAB patients achieved 100% patency before hospital discharge; however graft patency for the remaining 12 TECAB patients were not reported. Perioperative complications occurred in 1/34 patient (2.9%) which required intraoperative exploration via median sternotomy due to haemodynamic compromise. Postoperative complications were reported in 5 patients (14.7%). No wound infections were observed at the port side; however one case of superficial wound infection and one case of haematoma in the group was reported after femoral cannulation. The overall complication rates were higher compared to single-vessel MIDCAB. The investigators attributed this to the learning curve of performing TECAB due to the observation that most of the complications occurred within the first 20 patients of this study. In addition to the higher complication rates, mean operating times for single-vessel ( $4.2 \pm 0.9$  hours) and double-vessel ( $6.3 \pm 1.0$  hours) TECAB in this case series was markedly longer compared to MIDCAB or conventional CABG (Dogan et al. 2002).

In the study by Mohr et al. (2001), a subgroup of the patient cohort (n = 35) underwent TECAB to anastomose the left internal thoracic artery to the left anterior descending artery. Of the 35 patients who received TECAB, 27 patients underwent the procedure with an *arrested* heart while the remaining 8 patients underwent the procedure with a *beating* heart. The investigators reported that 22/27 patients who were assigned to TECAB on the arrested heart had completed the procedure. These patients had a conversion rate of 18.5%, 5/27 patients (minithoracotomy or sternotomy). There was no patient mortality and all patients were discharged with 100% patency. At 3 months, the patency rate was 95.4%, with only one case requiring reoperation. As with other studies (Argenziano et al. 2006, Dogan et al. 2002), the investigators highlighted that there was a substantial learning curve associated with the procedure, reflected by the long surgical durations ranging from 3.5 to 8 hours. A clear trend towards shorter surgical times was observed as experienced with the procedure increased, however the overall time still exceeds that required of a standard MIDCAB approach. Meanwhile in patients assigned to undergo TECAB with a beating heart, only 4/8 completed the procedure; 2 patients did not achieve adequate stabilisation while the other 2 patients had complications related to the anastomosis. In the remaining 4 patients who underwent beating heart TECAB, intraoperative angiography revealed 1 case of graft occlusion and one low-flow graft in another patient; therefore both were converted to MIDCAB. In the remaining 2 patients who completed the procedure, angiography revealed good runoff and widely patent anastomoses (50% initial patency rate, 2/4 patients) (Mohr et al. 2001).

In the seminal study by Falk et al. (2000), the investigators reported on the use of computer/robotic enhanced CABG in 66 patients, of these patients a subgroup of 22 patients (Group III in study) underwent *arrested* heart TECAB with the da Vinci system. During the procedure, 4/22 patients (18%) were converted to other techniques due to various reasons. At 3 months, all patients were free from angina and a 100% graft patency rate was achieved. One patient developed progressive dyspnoea 2-weeks postoperatively, and was diagnosed with pleural effusion and atelectasis of the lower left lobe which required multiple bronchoscopic interventions. The operative time was 330 minutes (5.5 hours), ranging from 220 to 507 minutes (Falk et al. 2000).

One study examined if TECAB can be utilised in combination with catheter-based interventions. The retrospective review by Katz et al. (2006) examined a subpopulation of patients (n = 27) with *multi-vessel* disease from the larger trial by Argenziano et al. (2006) who received a hybrid approach of *arrested* heart TECAB (LIMA-LAD graft) coupled with percutaneous coronary intervention (PCI) / stent placement of a second coronary artery. This study revealed that the use of the hybrid approach in the patient cohort resulted in no perioperative mortalities or neurological events. At 3-months follow-up, patient survival was 100%. However a total of 8 patients (29.6%) required target vessel reintervention. Overall, the investigators concluded that TECAB for LIMA-LAD grafting can be combined with catheter-based intervention to non-LAD targets in patients with multi-vessel disease. However, despite the low reintervention rates for the endoscopically placed graft (1/27 patients, 3.7%), stent intervention rates were higher than expected (3/10 patients [30%] for bare metal stents; 4/17 patients [23.5%] for drug-eluting stents) in this cohort (Katz et al. 2006).

## 2008 update

A search of relevant databases, online journals and the Internet was conducted in January 2008, following the recommendation in February 2007 that totally endoscopic coronary artery bypass surgery be monitored for 12 months. A total of four studies on the safety and effectiveness of this procedure were identified and retrieved.

### Safety and effectiveness issues

Mishra et al. (2006) reported on 13 patients (mean age  $56.3 \pm 7.2$  years) who underwent totally endoscopic coronary bypass (TECAB) using the da Vinci system. Twelve patients presented with single-vessel left anterior descending (LAD) artery disease and the remaining patient presented with single-vessel disease with additional proximal diagonal artery disease for which anastomosis was performed using the right internal mammary artery (IMA) on a beating heart. Eleven procedures were performed on beating hearts while two procedures were performed on arrested hearts.

Intraoperative complications requiring the conversion of the procedure from endoscopic to a conventional coronary artery bypass graft (CABG) were not encountered. All patients underwent successful robotic harvest of the IMA successfully. There were no reports of postoperative wound infection or mortality in patients who underwent TECAB. The mean duration of the operation was  $236 \pm 45$  minutes (range: 196 to 296 minutes). One patient who received beating heart TECAB required re-exploration for bleeding. In this patient the source of the bleeding was found to be an ITA branch. Bleeding was successfully repaired with no further complications. All patients sustained a short recuperation period and according to the authors were fit for discharge by the second postoperative day, however they were not released until the fourth. All 13 patients (100%) were complete to follow up (follow up range one to 24 months). During this time there was no recurrence of angina and no deaths were reported.

At three months postoperatively, all patients underwent an angiogram, of these 12 had 100% patency and one had 50% anastomotic narrowing. In this last patient with anastomotic narrowing angioplasty was immediately performed. Of the four patients who completed a two year follow-up, all were asymptomatic during regular exercise (Mishra et al. 2006).

In a comparative study conducted by de Canniere et al. (2007) 228 patients (mean age  $59.2 \pm 10.1$  years) with significant symptomatic coronary artery disease (90% single-vessel disease) underwent TECAB using the da Vinci surgical system. Patients were categorised in three groups; on-pump TECAB (group A), off-pump TECAB (group B) and those who underwent conversion from TECAB to conventional CABG before the completion of their surgical intervention (group C). The feasibility of the procedure was assessed by the ability to successfully complete TECAB without the need for conversion, the efficacy of the procedure was assessed by postoperative angiogram and/or stress electrocardiogram (ECG), and the safety of the procedure was assessed by the occurrence of major adverse cardiac events (MACEs) within a six month follow-up period (e.g. death, myocardial infarction, target vessel reintervention). A long term follow-up (mean follow up time 3.5 years) was also conducted on a random sample of 100 patients.

A total of 64/228 (28%) patients required conversion (group C). There was no significant difference in the conversion rate between group A and group B. Reasons for conversions included cannulation (group A), inadequate stabilization (group B), inappropriate patient conditions (group A) and bleeding at anastomosis (group A). At six months follow-up, the combined procedural efficacy (using angiogram and ECG) of TECAB was 97% with no

statistically significant difference between the three groups. Safety in terms of the occurrence of MACE at six months showed no statistically significant differences between groups A and B, groups A and C, and groups B and C. Of the patients who did not require a conversion, 9/164 (5%) had a MACE within the six month postoperative period (four in group A and five in group B). Of the patients who required a conversion, 3/64 (5%) reported a MACE. The perioperative safety of the procedure was determined by comparing the performed procedures with open CABG safety data from the Society of Thoracic Surgeons (STS) National Database for isolated single vessel disease. This revealed that perioperative MACE occurrence was similar between patients from the study (regardless of the group) and patients from the STS National Database. Mortality in group A and B occurred in one (1.1%) and two patients (2.2%), respectively with an additional mortality in two patients from group C (2.1%). The mortality in group A occurred 10 months after surgery from immunosuppressive therapy complications following kidney transplantation. In group B a patient scheduled for a hybrid procedure died of acute infarction before the planned percutaneous intervention could be performed. The second patient died from major, acute gastrointestinal bleeding with shock and cardiac arrest leading to a coma after cardiopulmonary resuscitation. The overall mortality rate for all three groups in the study was 2.1% compared with 2.4% for open CABG. Two patients (one in group A and B) had myocardial infarction within seven postoperative days (not statistically different to open CABG data), however this did not exceed the rate of myocardial infarction of CABG patients from the STS National Database. Overall, six patients underwent vessel reintervention within six months. Five of these underwent surgical reintervention while the sixth underwent stent placement. There was no statistically significant difference in the incidence of target vessel reintervention. Of the 100 long term follow-up (mean 3.5 years) patients, four had MACEs. This included two patients which required percutaneous coronary intervention, one who suffered myocardial infarction and one death of an unknown cause (de Canniere et al. 2007).

In a study conducted by Schachner et al. (2007), 85 patients (median age 58 years) underwent TECAB on an arrested heart using the da Vinci telemanipulator and remote access perfusion through the femoral vessels by balloon endo-occlusion of the ascending aorta and intermittent antegrade cardioplegia. Because cardiopulmonary bypass (CPB) and aortic endo-occlusion times are longer than conventional CABG techniques, this study aimed to investigate the effect of increased surgical procedure time on myocardial enzyme levels and the postoperative course.

Of the 85 patients undergoing TECAB, 13 (15.3%) required conversion to an open CABG. The mean duration of TECAB was 254 minutes (range: 178 minutes to 710 minutes), 114 minutes (range: 57 minutes to 428 minutes) for CPB and 65 minutes (range: 28 minutes to 230 minutes) for aortic endo-occlusion.

Postoperatively, the myocardial enzyme concentration for all patients was measured upon arrival at the intensive care unit (ICU) and four, eight, 12, 32 and 36 hours postoperatively. Forty-five per cent of patients had an increased peak creatine kinase MB (CK-MB) level greater than the 25 U/L cut off and 75% of patients had an increased peak troponin T level greater than the 0.039 µg/L cut off. Postoperative peak CK-MB levels significantly increased with totally endoscopic coronary bypass grafting duration ( $r = 0.588$ ,  $p < 0.001$ ), cardiopulmonary bypass time ( $r = 0.521$ ,  $p < 0.001$ ) and aortic endo-occlusion time ( $r = 0.400$ ,  $p < 0.001$ ). These increases then translated into prolonged stays in the ICU ( $r = 0.432$ ,  $p < 0.001$ ) prolonged ventilation time ( $r = 0.517$ ,  $p < 0.001$ ). Additionally, there was an association between increased postoperative peak CK-MB levels with increased postoperative length of stay  $r = 0.279$ ,  $p = 0.015$ ). There were no

statistically significant changes in the left ventricular ejection fraction as a result of the surgery (Schachner et al. 2007).

In a study conducted by Bonatti et al. (2007) 10 patients (mean age 59 years), presenting with either left main disease or left main equivalents, underwent totally endoscopic double-vessel coronary artery bypass grafting using the da Vinci system, remote-access perfusion and aortic balloon endo-occlusion. In each patient endoscopic placement of right IMA to the LAD in conjunction with left IMA grafting to an obtuse marginal (OM) branch was performed by a single surgeon. This procedure was successful in seven patients (70%). Three conversions to open CABG (via sternotomy) were required as a result of intraoperative complications and to prevent major vascular injury. These complications included injury to the LIMA to OM graft by an endoscopic instrument after successful completion of bypass conduit, OM graft revision due to anastomotic stenosis on the intraoperative angiographic control and an iliac artery level blockage of the RAP cannula advancement. There were no patient fatalities reported. Median ventilation time was 15 hours, median ICU stay was 41 hours and median patient discharge time was seven days post-op. The follow-up period ranged from one month to two years (median four months). During this time eight patients (80%) experienced no postoperative symptoms. However, two patients reported chest pain not associated with myocardial ischemia on stress tests. Other than these minor side effects, no major adverse cardiac or cerebrovascular episodes were observed throughout the entire observation period in any patients (Bonatti et al. 2007).

### **2008 HealthPACT Action**

The evidence regarding TECAB remains limited. Comparative clinical trials are required to compare TECAB with conventional CABG. These studies should ideally incorporate longer follow up periods, the effect of surgeon experience on TECAB outcomes and the effect of increased operation times on postoperative outcomes. Despite this, TECAB appears to offer a potentially safer and less invasive alternative to CABG.

This technology will therefore be monitored for 12 months.

### **Number of Studies Included**

Total number of studies	4
Level III-2 intervention evidence	1
Level IV intervention evidence	3

### **References**

Bonatti J, Schachner T, Bonaros N, Ohlinger A, Rutzler E, Feuchtner G, Kolbitsch C, Friedrich G, Bartel T, Pachingero and Laufer G. Robotic totally endoscopic double-vessel bypass grafting: A further step toward closed-chest surgical treatment of multivessel coronary artery disease. *Heart Surgery Forum* 2007; 10 (3): E239-E242.

de Cannière D, Wimmer-Greinecker G, Cichon R, Guliemos V, Van Praet F, Seshadri-Kreaden U and Falk V. Feasibility, safety, and efficacy of totally endoscopic coronary artery bypass grafting: Multicenter European experience. *Journal of Thoracic and Cardiovascular Surgery* 2007; 134 (3): 710-716.

Mishra YK, Wasir H, Sharma KK, Mehta Y and Trehan N. Totally endoscopic coronary artery bypass surgery. *Asian Cardiovascular and Thoracic Annals* 2006; 14 (6): 447-451.

Schachner T, Bonaros N, Ruetzler E, Weidinger F, Oehlinger A, Laufer G, Fredrich G and Bonatti J. Myocardial enzyme release in totally endoscopic coronary artery bypass grafting on the arrested heart. *Journal of Thoracic and Cardiovascular Surgery* 2007; 134 (4): 1006-1011.

## COST IMPACT

There are no cost-effectiveness studies on the use of the da Vinci system for TECAB. The da Vinci system costs approximately USD\$1,000,000 while specific instruments cost about USD\$1800 each (Wykypiel et al. 2003). The French CEDIT report estimated the costs likely to be associated with the use of a da Vinci surgical robotic system for cardiac surgery in the French healthcare system; the results are presented in Table 1 (CEDIT 2003):

**Table 1: Estimated costs of robotic cardiac surgery in the French healthcare system**

Item	Cost estimate (€)
Capital outlay (including warranty, shipping, installation, shipping)	1.1 – 1.2 million
maintenance contract	100,000 per year
total annual operating costs of already installed system	230,000
first year operating costs (including purchase of new system)	1.3 million
total annual additional cost incurred (annuity for depreciation, operating costs including financial charges)	365,000

The Medicare Benefits Schedule reimbursement fees for CABG are listed in Table 2:

**Table 2: Medical Benefits Schedule of fees for capsule and conventional endoscopy (Medicare Australia 2007)**

Category	Item Number	Benefit (AUD)	Number of Claims (July 2005 to June 2006)
Coronary artery bypass with cardiopulmonary bypass, using saphenous vein graft or grafts only, including harvesting of vein graft material where performed	38497	\$1809.30	524
Coronary artery bypass with the aid of tissue stabilisers, <i>performed without cardiopulmonary bypass</i> , using saphenous vein graft or grafts only, including harvesting of vein graft material where performed, either via a median sternotomy or other minimally invasive technique and where a stand-by perfusionist is present	38498	\$1809.30	15
Coronary artery bypass with cardiopulmonary bypass, using single arterial graft, with or without vein graft or grafts, including harvesting of internal mammary artery or vein graft material where performed	38500	\$1944.00	2390
Coronary artery bypass with the aid of tissue stabilisers, <i>performed without cardiopulmonary bypass</i> , using single arterial graft, with or without vein graft or grafts, including harvesting of internal mammary artery or vein graft material where performed, either via a median sternotomy or other minimally invasive technique and where a stand-by perfusionist is present,	38501	\$1944.00	244
Coronary artery bypass with cardiopulmonary bypass, using 2 or more arterial grafts, with or without vein graft or grafts, including harvesting of internal mammary artery or vein graft material where performed	38503	\$2110.75	2443
Coronary artery bypass with the aid of tissue stabilisers, <i>performed without cardiopulmonary bypass</i> , using 2 or more arterial grafts, with or without vein graft or grafts, including harvesting of internal mammary artery or vein graft material where performed, either via a median sternotomy or other minimally invasive technique and where a stand-by perfusionist is present	38504	\$2110.75	190
Re-operation of patient diseased coronary artery bypass vein graft or grafts, dissection, disconnection and oversewing of	38637	\$490.00	151

## **ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS**

No issues were identified from the retrieved material.

## **OTHER ISSUES**

Several authors in the study by Katz et al. (2006) are affiliated with Intuitive Surgical Inc., the manufacturer of the da Vinci system: Dr. Murphy and Dr. Srivastava are consultants for Intuitive Surgical Inc while Ms Kreaden is an employee of Intuitive Surgical.

## **RECOMMENDATION:**

Based on the included studies, TECAB on the *arrested* heart with the da Vinci system can be performed with acceptable safety and efficacy by surgeons who are appropriately/adequately trained with the equipment. Overall, the results of these studies compare reasonably with available data from studies of coronary bypass surgery by minimally invasive (MIDCAB) and conventional approaches. However, it should be noted that TECAB is associated with substantially longer surgical times, which may be of concern. At least one study has highlighted increased perioperative transfusion rates (Argenziano et al. 2006) which may be a direct consequence of the longer procedural times.

Despite attempts to perform TECAB on the *beating* heart, the success rate remains low (Mohr et al. 2001). Therefore the benefits associated with *beating* heart TECAB, reduced trauma and decreasing surgical time (no cannulation, reperfusion and rewarming required), remains unattainable at this point time. Further studies are required to determine if the high costs associated with the da Vinci system are justified and if the clinical benefits are substantial enough to justify the adoption of this technology at this stage. Based on the amount of evidence available, HealthPACT recommends that the technology be monitored.

- |  |  |
|--|--|
| <input type="checkbox"/> Horizon Scanning Report | <input type="checkbox"/> Full Health Technology Assessment |
| <input checked="" type="checkbox"/> Monitor      | <input type="checkbox"/> Archive                           |
| <input type="checkbox"/> Refer                   | <input type="checkbox"/> Decision pending                  |

## **SOURCES OF FURTHER INFORMATION:**

Intuitive Surgical Inc. Last updated 2007. <http://www.intuitivesurgical.com/index.aspx> [Accessed January 2007].

Falk V, Jacobs S, Gummert JF, Walther T, Mohr FW. Computer-enhanced endoscopic coronary artery bypass grafting: the da Vinci experience. *Seminars in Thoracic and Cardiovascular Surgery* 2003; 15(2): 104-111.

## **LIST OF STUDIES INCLUDED**

Total number of studies            5  
Level IV intervention evidence

## **SEARCH CRITERIA TO BE USED:**

Coronary Artery Bypass/methods\*  
Coronary Artery Bypass/instrumentation  
Coronary vessels/surgery  
Endoscopy/methods\*  
Robotics\*  
TECAB  
Total endoscopic coronary bypass  
da Vinci

## REFERENCES:

- Australian Institute of Health and Welfare (AIHW): Coronary Heart Disease. Last updated 2006. <http://www.aihw.gov.au/cvd/majordiseases/coronary.cfm> [Accessed December 2006].
- Argenziano M, Katz M, Bonatti J, Sricastava S, Murphy D, Poirier R, Loulmet D, Siwek L, Kreaden U, Ligon D. Results of the prospective multicenter trial of robotically assisted totally endoscopic coronary artery bypass grafting. *Annals of Thoracic Surgery* 2006; 81(5): 1666-1675.
- CEDIT. Robotic surgery using telemanipulators. Paris: Committee for Evaluation and Diffusion of Innovative Technologies - Assistance Publique Hôpitaux de Paris. Last updated 2003. [http://cedit.aphp.fr/english/f\\_pub\\_cedit\\_menu.html](http://cedit.aphp.fr/english/f_pub_cedit_menu.html) [Accessed January 2007].
- Dogan S, Aybek T, Andreßen E, Byhahn C, Mierdl S, Westphal K, Matheis G, Moritz A, Wimmer-Greinecker G. Totally endoscopic coronary artery bypass grafting on cardiopulmonary bypass with robotically enhanced telemanipulation: Report of forty-five cases. *Journal of Thoracic and Cardiovascular Surgery* 2002; 123(6): 1125-1131.
- Falk V, Diegeler A, Walther T, Banusch J, Brucerius J, Raumans J, Autschbach R, Mohr FW. Total endoscopic computer enhanced coronary artery bypass grafting. *European Journal of Cardio-thoracic Surgery* 2000; 17(1): 38-45.
- FDA: Food and Drug Administration. Computer-assisted surgery: An update. Last updated 2005. [http://www.fda.gov/fdac/features/2005/405\\_computer.html](http://www.fda.gov/fdac/features/2005/405_computer.html) [Accessed January 2007].
- Katz MR, Can Praet F, de Canniere D, Murphy D, Siwek L, Seshadri-Kreaden U, Friedrich G, Bonatti J. Integrated coronary revascularization: Percutaneous coronary intervention plus robotic totally endoscopic coronary artery bypass. *Circulation* 2006; 114(1 Suppl): 473-476.
- Medicare Australia: Medicare benefits Schedule. Last update 2007. <http://www9.health.gov.au/mbs/> [Accessed January 2007].
- Mohr FW, Falk V, Diegeler A, Walther T, Gummert JF, Bucarius J, Jacobs S, Autschbach R. Computer-enhanced "robotic" cardiac surgery: experience in 148 patients. *Journal of Thoracic and Cardiovascular Surgery* 2001; 121(5): 842-853.
- Wykypiel H, Wetscher GJ, Klaus A, Schmid T, Gadenstaetter M, Bodner J, Bodner E. Robot-assisted laparoscopic partial posterior fundoplication with the DaVinci system: initial experiences and technical aspects. *Langenbecks Archives of Surgery* 2003; 387(11-12):411-416.

# **PRIORITISING SUMMARY (2009 UPDATE)**

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**NAME OF TECHNOLOGY:** **TOTALLY ENDOSCOPIC CORONARY ARTERY BYPASS SURGERY (DA VINCI SYSTEM)**

**PURPOSE AND TARGET GROUP:** **PATIENTS SUFFERING FROM CORONARY ARTERY DISEASE**

## **2009 SAFETY AND EFFECTIVENESS ISSUES**

A search of relevant databases, online journals and the Internet was conducted in February 2009, following the recommendation in February 2008 that totally endoscopic coronary artery bypass surgery using the da Vinci system be monitored for 12 months. Three case series studies on the safety and effectiveness were identified including one study which was only available in abstract form.

A five year follow-up of 41 patients (36 male and 5 female) who underwent totally endoscopic coronary artery bypass for isolated high-grade lesions of the left anterior descending coronary artery was reported by Kappert et al (2008). The patients had single (95.2%) and double vessel (4.8%) coronary artery disease involving primarily the left anterior descending artery and presented with a low baseline mean EuroSCORE of  $2.1 \pm 0.1$ . The first eight patients underwent the procedure under arrested heart conditions, while the remaining 33 patients underwent the procedure under beating heart off-pump conditions.

The mean follow-up period for the patients was  $69 \pm 7.4$  months (range: 60 to 85 months) and during this time three deaths were reported, however, each of the deaths were due to non-cardiac related causes. During the follow-up period, there were two cases of myocardial infarctions (occurring at six and 19 months post-operatively), however in both cases the infarct was located outside the region of the bypassed target vessels. Reintervention of the left anterior descending artery was required in five patients resulting from graft occlusion ( $n = 2$ ), significant anastomotic stenosis ( $n = 2$ ) and de novo lesion of the distal LAD. Therefore at 69 months follow-up, 36 (87.8%) patients were free from reintervention. The overall patency rate was reported at 71.4% although this utilised data from 10 out of 14 patients for whom angiography data was available. The reported rate of freedom from major adverse events (myocardial infarction, reintervention and cardiac related mortality) was 75.6% (31 out of 41 patients).

Bonatti et al (2008a) conducted a study to assess the influence of specific preventive measures on procedure time and postoperative outcome in totally endoscopic left internal mammary artery (IMA) to left anterior descending artery (LAD) grafting on the arrested heart. A total of 70 patients (58 male and 12 female) of mean age 59 years were included in this study. The measures applied included: (1) introduction of a fixed team of surgeons from case 14 onwards; (2) application of fibrin glue to seal the anastomosis at case 28 onwards; and (3) use of a fourth port for transthoracic assistance from case 49 onwards.

The results of the study demonstrated that following implementation of the stable team of surgeons, a significant improvement in intraoperative outcomes including operating time (420 versus 305 minutes;  $p = 0.001$ ), cardiopulmonary bypass time (182 versus 98 minutes;  $p < 0.001$ ), aortic endo-occlusion time (91 versus 60 minutes;  $p = 0.003$ ) and patients requiring conversion or revision on table (39% versus 9%;  $p = 0.006$ ) was observed. Post-operatively,

application of this measure resulted in significantly improved ventilation time (14 versus 7 minutes;  $p = 0.014$ ) and shorter hospital stay (7 versus 6 days;  $p = 0.039$ ).

Application of perianastomotic fibrin glue resulted in significant intraoperative improvements including operating time (383 versus 305;  $p = 0.013$ ), cardiopulmonary bypass time (138 versus 98 minutes;  $p = 0.009$ ) and patients requiring conversion or revision on table (26% versus 7%;  $p = 0.038$ ). Application of the fibrin glue also resulted in significant improvements in the percentage of patients requiring revision for bleeding (22% versus 5%;  $p = 0.048$ ) as well as significant reductions in length of time spent in the intensive care unit (24 versus 19 days;  $p = 0.038$ ) and hospital (7 versus 6 days;  $p = 0.002$ ).

In comparison to cases performed before the use of a fourth port for transthoracic assistance, the application of this measure predominately improved intraoperative outcomes including operating time (352 versus 282 minutes;  $p = 0.001$ ), cardiopulmonary bypass time (115 versus 91 minutes;  $p = 0.019$ ), aortic endo-occlusion time (70 versus 51 minutes;  $p = 0.006$ ) and anastomotic time (35 versus 25 minutes;  $p < 0.001$ ). This measure also resulted in a decrease in the length of hospital stay from a mean of seven days to five days ( $p = 0.001$ ).

Throughout the entire series of patients, there were no reports of death, stroke or multi-organ failure. Similarly, no target vessel re-intervention was required after discharge.

In a second study by Bonatti et al (2008b) available only in abstract form, five patients underwent simultaneous robotic TECAB and percutaneous coronary intervention. Patients received a left internal mammary artery bypass graft to the left anterior descending artery and underwent placement of a Rapamycin coated into stenotic non left anterior descending artery targets. The study aimed to assess the feasibility of performing a simultaneous TECAB and PCI procedures. The results demonstrated that a simultaneous procedure was feasible in four patients. In one patient the procedure required conversion to a double CABG operation. No significant post-operative clinical complications were reported, although no definition of the term 'significant' was provided. Patients were discharged from the intensive care unit after 19 hours (range: 18 to 61 hours) and from the hospital after six days (range: five to seven days). Post-operatively, at six months, all patients were free from angina.

## **2009 SUMMARY OF FINDINGS**

The studies included in this update support the information from the original Prioritising Summary that TECAB using the da Vinci systems appears to be a safe technique. Furthermore, the study by Bonatti et al (2008a) suggests that there are potential measures that can be taken to improve both the intraoperative and postoperative outcomes of this procedure. Unfortunately, there remains a lack of comparative evidence with all the evidence for this update coming from case series studies.

## **2009 HEALTHPACT ACTION**

Due to the lack of additional evidence on TECAB, this topic will be archived. However, based on the potential of TECAB as well as other techniques which make use of the da Vinci surgical system, procedures which make use of the da Vinci system will be monitored.

## **2009 NUMBER OF STUDIES INCLUDED**

Total number of studies	3
Level IV intervention evidence	3

## 2009 REFERENCES

Bonatti J, Schachner T, Bonaros N, Oehlinger A, Ruetzler E, Friedrich G, Feuchtner G, Laufer G. How to improve the performance of robotic totally endoscopic coronary artery bypass grafting. *The American Journal of Surgery* 2008a; 195(5): 711 – 716.

Bonatti J, Schachner T, Bonaros N, Jonetzko P, Ohlinger A, Ruetzler E, Kolbitsch C, Feuchtner G, Laufer G, Pachinger O, Friedrich G. Simultaneous hybrid coronary revascularization using totally endoscopic left internal mammary artery bypass grafting and placement of rapamycin eluting stents in the same interventional session. The COMBINATION pilot study (Abstract). *Cardiology* 2008b; 110(2): 92 – 95.

Kappert U, Tugtekin S, Cichon R, Braun M, Matschke K. Robotic totally endoscopic coronary artery bypass: a word of caution implicated by a five-year follow-up. *The Journal of Thoracic and Cardiovascular Surgery* 2008; 135(4): 857 – 862.