



Australian Government
Department of Health and Ageing



Horizon Scanning Technology
Prioritising Summary
Totally endoscopic coronary artery bypass
surgery

February 2007



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



**Royal Australasian
College of Surgeons**

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Enquiries about the content of the report should be directed to:

HealthPACT Secretariat
Department of Health and Ageing
MDP 106
GPO Box 9848
Canberra ACT 2606
AUSTRALIA

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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.

This Horizon scanning prioritising summary was prepared by Mr. Irving Lee from the Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S).

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 endothoracic 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 ± 89 minutes (mean \pm SD) (range: 200 – 600 minutes) and the length of hospitalisation was 5.1 ± 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 ± 0.9 hours) and double-vessel (6.3 ± 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).

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

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Medicare Australia: Medicare benefits Schedule. Last update 2007. <http://www9.health.gov.au/mbs/> [Accessed January 2007].

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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.