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Ongoing Procedure Development in Robotically Assisted Totally Endoscopic Coronary Artery Bypass Grafting (TECAB)

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ABSTRACT

Background: Totally endoscopic coronary artery bypass grafting (TECAB) using robotics requires stepwise introduction into a heart surgery program. It is the aim of this study to evaluate the state of procedure development after continued application of telemanipulation techniques in the clinical setting. We also sought to assess perioperative and intermediate term clinical results after robotically assisted CABG.

Patients and methods: From June 2001 to March 2005, robotically assisted CABG using the daVinci™ system was carried out in 107 patients with single and multivessel coronary artery disease. The following procedures were performed: robotically assisted endoscopic left internal mammary artery (LIMA) harvesting and completion of the procedure as conventional CABG, MIDCAB, or OPCAB (n = 22), robotically assisted suturing of LIMA-to-LAD anastomoses during conventional CABG (n = 28), TECAB on the arrested heart using remote access perfusion (n = 48), TECAB on the beating heart using an endostabilizer (n = 8), takedown of adhesions (TECAB intended) (n = 1).

Results: Hospital mortality was 0% and cumulative risk adjusted mortality reached 1.6 lives saved versus EuroSCORE predictions. Undesirable surgical events (USE) such as conversion, on table revision, or postoperative revision procedures occurred in 34 out of 107 (32%) patients. Median ventilation time and ICU stay, however, were 11(0-278) hours and 21(11-389) hours, respectively. Cumulative 3 years survival was 100% and freedom from angina at 3 years was 97%.

Conclusions: We conclude that despite being surgically challenging robotically assisted coronary artery surgery can be implemented with acceptable safety. TECAB procedures have reached a reproducible state. Perioperative mortality after robotically assisted CABG may be lower than predicted. Intermediate term clinical results are very satisfactory.

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BACKGROUND

After unsuccessful attempts to carry out totally endoscopic coronary artery bypass grafting (TECAB) procedures using conventional thoracoscopic instrumentation in the mid-1990s, robotic technology has enabled performance of such operations [Loulmet 1999]. Only a few groups worldwide, however, have embarked on this technology and few series on robotic CABG are published in the current literature. Initial reports have shown clinical results that were absolutely acceptable [Dogan 2002, Falk 2000, Kappert 2001]. The implementation process of TECAB, however, has been slow, most probably due to the fact that costs for the device and for the procedures are significant. In addition, the operations are time consuming as well as technically demanding. Data on intermediate term results after application of robotic techniques in CABG are very sparse in the literature.

The aim of the current study is to describe a larger cohort of patients with coronary artery disease in whom robotic technology was applied in order to develop totally endoscopic procedures. It is also the intention to describe the process of TECAB implementation and to evaluate intermediate term postoperative clinical results.

PATIENTS AND METHODS

From June 2001 to March 2005, 107 patients with single and multivessel coronary artery disease received CABG procedures that involved application of the daVinci™ telemanipulation device (Intuitive Surgical, Sunnyvale, CA). Demographic data are listed in Table 1. All patients gave written informed consent for application of robotic techniques and ethics committee approval was obtained for performance of totally endoscopic procedures.

Stepwise Introduction of TECAB Operations

A stepwise approach to TECAB was taken. Procedure modules such as LIMA takedown and robotic anastomotic suturing in sternotomy CABG were carried out during the initial phase of TECAB development but also intermittently thereafter. Arrested heart TECAB was first carried out in

Table 1. Patient Demographics*

Age, y	60 (38-76)
Male	82 (77%)
Female	25 (23%)
Height, cm	172 (53-190)
Weight, kg	77 (48-102)
BMI, kg/m^2	26 (19-38)
Hypertension	83 (78%)
Hypercholesterolemia	82 (76%)
Hypertriglyceridemia	5 (5%)
Smoking	42 (39%)
DM	9 (8%)
History of MI	32 (30%)
Previous PTCA/stent	24 (23%)
LVEF, %	62 (36-86)
COPD	18 (17%)
Preop creatinine level, mg%	1.04 (.58-1.53)
CVD	3 (3%)
PVD	3 (3%)
EuroSCORE	1 (0-7)

*BMI indicates body mass index; DM, diabetes mellitus; MI, myocardial infarction; PTCA, percutaneous transluminal coronary angioplasty; LVEF, left ventricular ejection fraction; COPD, chronic obstructive pulmonary disease; CVD, cerebrovascular disease; PVD, peripheral vascular disease.

2001, beating heart TECAB and multivessel TECAB were first performed in 2004. The operations are listed in Table 2. A detailed description of the different procedure modules has been reported by us in part previously [Bonatti 2004, Ott 2002]. For beating heart TECAB we basically followed the technique described by the Dresden and Leipzig groups [Kappert 2001, Mohr 2001]. In arrested heart TECAB procedures the ESTECH remote access perfusion system was applied [Schachner 2004]. Intraoperative angiography was carried out in patients in whom grafts were sutured robotically.

Table 2. Robotically Assisted Procedures*

Implementation steps	
Intraoperative exclusion (takedown of adhesions)	1 (1%)
Robotic LIMA takedown, completion as CABG/OPCAB (patients with double or triple vessel disease)	14 (13%)
Robotic LIMA-LAD suturing during sternotomy CABG (patients with double or triple vessel disease)	28 (26%)
Limited access/totally endoscopic	
MIDCAB using robotic LIMA takedown	8 (7%)
Arrested heart TECAB (AH-TECAB)	48 (46%)
Beating heart TECAB (BH-TECAB)	8 (7%)
Total	107 (100%)

*LIMA indicates left internal mammary artery; CABG, coronary artery bypass grafting; OPCAB, off pump coronary artery bypass grafting; LAD, left anterior descending artery; MIDCAB, minimally invasive direct coronary artery bypass; AH-TECAB, arrested heart totally endoscopic coronary artery bypass; BH-TECAB, beating heart coronary artery bypass.

Table 3. Increase of Totally Endoscopic CABG Procedures Throughout the Implementation Process of TECAB

	Totally Endoscopic Procedure		
Year	Yes	No	Total
2001	2 (13%)	13 (87%)	15
2002	13 (37%)	22 (63%)	35
2003	14 (64%)	8 (36%)	22
2004	21 (75%)	7 (25%)	28
2005	6 (86%)	1 (14%)	7
Total	56 (52%)	51 (48%)	107

Definitions

Major adverse cardiac and cerebrovascular events (MACCE) were defined as the occurrence of death, myocardial infarction, or the necessity of an unplanned surgical or percutaneous coronary revascularization procedure during or after performance of a robotically assisted CABG operation.

Undesirable surgical events (USE) were defined as the occurrence of MACCE and/or the necessity for conversion to a larger thoracic incision during an intended totally endoscopic operation and/or the intra- or perioperative occurrence of bleeding from any part of the operative field requiring surgical revision.

Statistics

Categorical variables are given as absolute numbers and percentages, continuous variables are shown as median and range. Comparisons of categorical data were carried out using the Chi-square test or Fisher exact test where appropriate. Continuous variables were compared using the Mann-Whitney-U test. For calculation of risk-adjusted mortality CRAM plots the predictions by the linear EuroSCORE were applied. Cumulative survival, freedom from angina, and freedom from MACCE, were assessed using life table analysis. A P-value of <.05 was regarded as significant.

RESULTS

The introduction of TECAB followed a stepwise introduction protocol. Table 3 shows that the percentage of totally endoscopic procedures increased significantly from 13% in the first year of application to 86% currently ($P < .001$).

Procedure time including intraoperative angiographic studies for quality control was 360 (225-724) minutes in the whole patient cohort. In totally endoscopic operations, conversions to a larger thoracic incision during conduct of the procedure were necessary in 8/56 (14%) and there were 6/56 (11%) graft revisions on table after completion of the primary intervention. Further perioperative results are listed in Table 4. The rate of USE as a common perioperative endpoint was 34/107 (32%). No specific demographic risk factor could be identified for the occurrence of USE, and totally endoscopic procedures did not show an increased USE rate (Table 5).

Figure 1 depicts a cumulative risk-adjusted mortality (CRAM)—plot of the whole patient series. 1.6 theoretical deaths predicted by EuroSCORE did not occur.

Three year cumulative survival after robotically assisted CABG was 100%. As shown in Figures 2 and 3, three years

Table 4. Perioperative Results*

Blood transfusion (Units)	1 (0-21)
Reoperation for bleeding	8 (7%)
CK (max), U/L	700 (26-7672)
CK-MB (max), U/L	26 (7-242)
Myocardial infarction	3 (3%)
IABP	1 (1%)
Atrial fibrillation	16 (15%)
Ventilation time, h	11 (0-278)
Tracheostomy	2 (2%)
Pneumonia	4 (4%)
Forced diuresis	9 (8%)
Renal failure requiring hemofiltration	2 (2%)
TIA	1 (1%)
Stroke	0 (0%)
ICU stay, h	21 (11-389)
Hospital stay, d	8 (2-25)

IABP indicates intraaortic balloon pump; TIA, transitory ischemic attack; ICU, intensive care unit.

freedom from angina and freedom from major adverse cardiac and cerebral events (MACCE) were 97% and 84%, respectively. At follow-up there were no target vessel reinterventions in cases where coronary anastomoses were sutured robotically or repaired perioperatively after primary robotic suturing.

DISCUSSION

Patient Selection

As can be seen from the demographic profile of this patient series, relatively young patients with few comorbidities and a low median EuroSCORE were selected for our first steps into robotic CABG. Knowing that long operations and conversions were to be expected we followed this strategy in order to work with adequate biological reserves of the patients.

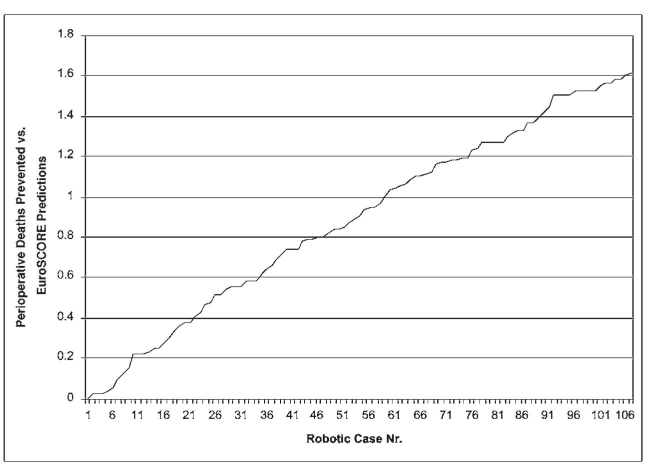

Figure 1. CRAM (cumulative risk adjusted mortality) plot for the first 107 CABG patients in whom robotic technology was applied.

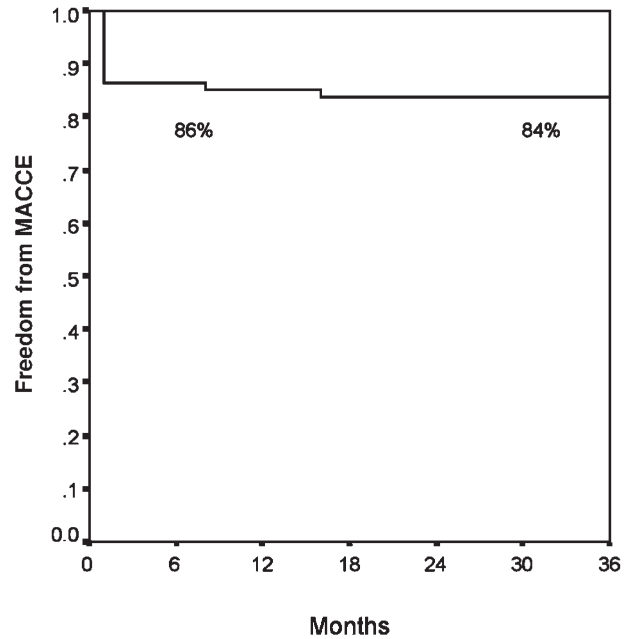

Figure 2. Freedom for major adverse cardiac and cerebrovascular events (MACCE) in patients undergoing robotically assisted coronary surgery. Note that the majority of MACCE occurred intra- or postoperatively and received immediate treatment. At follow-up only few further MACCE were noted.

Stepwise Introduction of TECAB

We and others have shown that TECAB should be implemented in a stepwise fashion including limited procedure modules that are carried out during standard CABG [Bolton 2004, Bonatti 2004, Falk 2000, Kappert 2001, Mohr 2001].

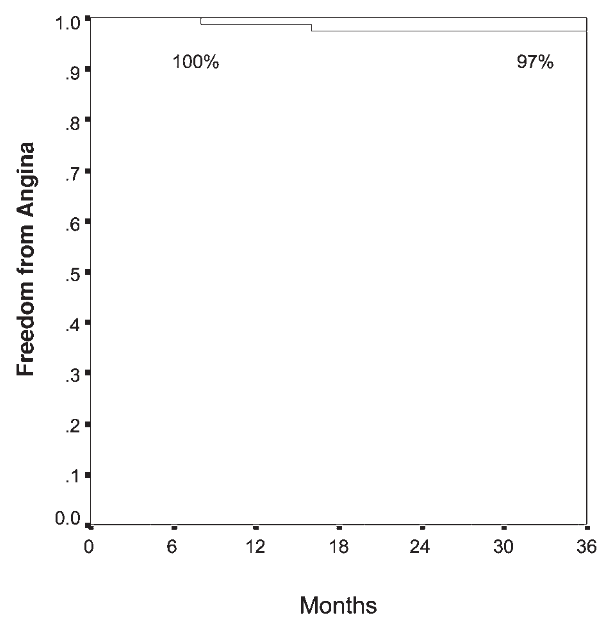

Figure 3. Freedom from angina in patients undergoing robotically assisted coronary surgery.

Table 5. Risk Factors for the Occurrence of Undesirable Surgical Events (USE)*

Variable	Patients with USE	Patients without USE	
Age, y	59 (42-76)	60 (38-76)	*P* = NS
Male	24 (71%)	58 (80%)	
Female	10 (29%)	15 (20%)	*P* = NS
Height, cm	172 (156-186)	172 (153-190)	*P* = NS
Weight, kg	75 (52-100)	78 (48-102)	*P* = NS
BMI, kg/m^2	26 (20-38)	26 (19-36)	*P* = NS
Number of cardiovascular risk factors	2 (0-4)	2 (0-4)	*P* = NS
Hypertension	55 (75%)	28 (82%)	*P* = NS
Hypercholesterolemia	56 (77%)	26 (77%)	*P* = NS
Hypertriglyceridemia	3 (9%)	2 (3%)	*P* = NS
Smoking	16 (47%)	26 (36%)	*P* = NS
DM	2 (6%)	7 (10%)	*P* = NS
Preop Creatinine, mg/dL	1.03 (.65-1.37)	1.05 (.58-1.53)	*P* = NS
History of MI	9 (27%)	23 (31%)	*P* = NS
St.p. PTCA/Stent	11 (32%)	13 (18%)	*P* = NS
LVEF, %	65 (45-80)	60 (36-86)	*P* = NS
CVD	1 (1%)	2 (6%)	*P* = NS
History of stroke	1 (1%)	0 (0%)	*P* = NS
Totally endoscopic procedure	19 (56%)	37 (51%)	*P* = NS
Use of CPB	30 (88%)	55 (75%)	*P* = NS
Use of remote access perfusion	16 (47%)	31 (42%)	*P* = NS

*BMI indicates body mass index; DM, diabetes mellitus; MI, myocardial infarction; PTCA, percutanerous transluminal coronary angioplasty; LVEF, left ventricular ejection fraction; CVD, cerebrovascular disease; CPB, cardiopulmonary bypass.

This stepwise approach seems to enable acceptable safety and controlled learning curves. More than half of the procedures were carried out as totally endoscopic operations during the third year of application. In the current phase we still have not reached a 100% level. It can be anticipated that a certain percentage of limited robotic procedures will further be carried out as new surgeons need to be trained in using telemanipulation techniques.

Intraoperative and Postoperative Course

Long operative times are a fact in robotically assisted CABG. Learning curves and reduction of procedure times have been observed by the majority of groups working with this technology [Falk 2000, Kappert 2001, Mohr 2001]. Nevertheless, our overall surgery times in the 6-hour range indicate that robotic CABG is and will probably remain a "long-distance flight" in coronary surgery and that OR capacity must allow corresponding OR time if such a program is started.

High rates of conversions to larger incisions and surgical revision procedures immediately postop are a known fact in the current phase of TECAB development. Other groups have described conversion rates in the 18% to 34% range [Dogan 2002, Falk 2000, Kappert 2001]. Accordingly, we had to deal with a 26% rate of patients in whom a totally endoscopic approach was intended but a minithoracotomy or a sternotomy had to be performed at last. The rate of USE as a common endpoint is high. It may be of note, however, that despite this high perioperative event rate the final clinical outcome is very good. Difficulties were detected early and repaired immediately. We found no specific patient-related risk factor for the occurrence of USE and a totally endoscopic approach, use of the remote access perfusion system, and use of the cardiopulmonary bypass could not be identified as risk factors either.

Our perioperative results concerning ventilation time, ICU stay and length of hospital stay are well in accordance with data reported by the Leipzig group in 2000 [Falk 2000] and the Dresden group in 2001 [Kappert 2001].

Mortality

Introduction of new procedures or technology into a heart surgery program carries the risk of increased perioperative mortality. Sergeant and co-workers demonstrated by CRAM plots that the innovative technique of CABG without the use of the heart lung machine can be implemented with only minor compromises concerning mortality in the very early phase of procedure introduction [Sergeant 2001]. It was gratifying for us that mortality was not increased during implementation of robotic techniques into our CABG program and that deaths predicted by EuroSCORE were even prevented. We attribute this to careful conduct of the procedures allowing long operative times, to the rigorous methods of quality control that were applied, and to close observation of the patients postoperatively with timely surgical reaction if necessary.

Intermediate Term Results

It was satisfactory to see that survival at 3 years postoperatively was 100%. Ninety-seven percent of our patients were free of angina at 3 years. Little data on intermediate term results after application of robotic techniques in CABG is available in the literature. Falk and co-workers reported 3 months freedom from angina of 100%, and we also achieved freedom from angina of 100% even at 6 months postoperatively [Falk 2000]. Kappert, by comparison, noted 81% of patients to be in CCSC class I at 3 months follow-up, the majority of patients had received MIDCAB operations with robotic left internal mammary artery takedown. Target vessel reinterventions were necessary only in this group of patients [Kappert 2001].

Freedom from MACCE at 3 years after robotically assisted coronary revascularization was 84% in our series. This seems to be well comparable with 3 year results that were obtained in the surgical arm of the ARTS trial [Legrand 2004]. In our patients the rate of multivessel disease was lower than in the cited study. It needs to be pointed out, however, that a substantial number of MACCE was detected intra-operatively in our series and was controlled immediately. Only 2 MACCE events occurred thereafter during the 3 year follow-up course.

CONCLUSION

We conclude that stepwise application of robotic technology toward TECAB enables a controlled implementation process. Reproducible performance of TECAB procedures has become a reality. As observed by others a significant rate of undesirable surgical events including conversions and on table as well as postoperative revision procedures should be expected. These events, however, do not translate into increased mortality and do not seem to compromise an adequate revascularization result. Risk-adjusted mortality may even be lower than predicted if patient selection is adequate and if rigorous methods of intra-operative quality control and immediate correction of graft failures are applied. Intermediate term clinical results as expressed by freedom from angina are very satisfactory.

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