

Surgery for Acquired Cardiovascular Disease

Robotic totally endoscopic coronary artery bypass: A word of caution implicated by a five-year follow-up

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Objective: Robotic totally endoscopic coronary artery bypass of the left anterior descending artery has been introduced in the clinical setting using a wrist-enhanced computer-assisted device to provide a minimally invasive therapeutic approach. Early clinical results were focused on the initial hospital course of patients. This report describes the first 5-year follow-up of patients after totally endoscopic coronary artery bypass in a single center.

Methods: From May 1999 to June 2001, 41 patients (36 male, 5 female; mean age 60.6 ± 8.9 years) underwent totally endoscopic coronary artery bypass for isolated high-grade lesions of the left anterior descending coronary artery by means of the da Vinci system (Intuitive Surgical, Inc, Mountain View, Calif). Clinical follow-up was performed 5 years after the operation. End points of the follow-up were freedom from major adverse events such as death, myocardial infarction, and repeated revascularization of the left anterior descending artery.

Results: Hospital survival was 100%. Overall survival after 5 years was 92.7% (38/41 patients). Three (7.3%) patients died of noncardiac causes. Freedom from reintervention of the left anterior descending artery after a mean of 69 ± 7.4 months was 87.2% (36/41 patients). Freedom from any major adverse events during the whole follow-up was 75.7% (31/41 patients).

Conclusion: Endoscopic surgery on the beating heart remains the ultimate goal for minimally invasive coronary artery surgery. The clinical outcomes and need for reintervention of the target vessel leave room for improvement and may be considered reflective of early experiences typically associated with dramatic departure from conventional therapy. Moving forward, advances in instrumentation and anastomotic technology seem to be essential for reproducible and reliable coronary anastomosis in a totally endoscopic approach.

Robotic technology was introduced into cardiac surgery in 1999. The da Vinci (Intuitive Surgical Inc, Sunnyvale, Calif) telemanipulator system was designed to allow the surgeon to perform totally endoscopic coronary artery bypass grafting (TECAB).¹⁻³ These design criteria were validated in the initial clinical trials resulting in European and Food and Drug Administration approval for minimally invasive cardiac surgery. These early trials mainly focused on initial outcomes until hospital discharge.¹⁻⁴

Long-term assessment of this surgical approach is still pending. The Heart Center Dresden was one of the early adopters of this technology and performed the TECAB procedure in a number of patients requiring single-vessel revascularization, initially

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Abbreviations and Acronyms

LAD	= left anterior descending coronary artery
MACE	= major adverse cardiac events
MIDCAB	= minimally invasive direct coronary artery bypass
TECAB	= totally endoscopic coronary artery bypass

on-pump and later using the off-pump technique.³ The following describes the 5-year clinical results from this initial single-center TECAB series.

Patients and Methods

Forty-one patients (36 male, 5 female; average age 60.6 ± 8.9 years) with single- (95.2%) and double-vessel (4.8%) coronary artery disease involving primarily the left anterior descending artery (LAD) underwent a TECAB procedure with a wrist-enhanced coronary anastomosis by means of the da Vinci system (Intuitive Surgical, Inc, Mountain View, Calif) between May 1999 and June 2001. The 41 patients accounted for 1.2% of all patients who underwent surgical treatment for coronary artery disease during the same period at the same institution.

Demographic data of these patients are presented in Table 1 and show that this patient cohort presented a low rate of comorbidities and risk factors, as illustrated by the comparably low EuroSCORE of 2.1 ± 0.1 . The operative data regarding target vessel and conduit selection are shown in Table 2.

The initial 8 (19.6%) patients received the TECAB technique on the arrested heart with an endovascular bypass system. In 33 (80.4%) patients a beating-heart off-pump TECAB procedure was performed. Stabilization was accomplished with 4 different iterations of endoscopic stabilizers, all of which need to be considered early prototypes (Figure 1).

Follow-up information on patients was obtained in June 2006 and was complete in all 41 patients having undergone this particular procedure. The mean follow-up period was 69 ± 7.4 months with a range of 60 to 85 months.

Sampling of data was accomplished by reviewing hospital records and by performing a telephone interview with the patient directly, the patients' relatives, or the patients' referring physicians.

This clinical evaluation was approved by the ethics committee of the University of Leipzig ("Study on the Clinical Use of a Telemicro-manipulator in Minimally Invasive Cardiac Surgery"; Int. Reg. No. 721, approval date May, 19, 1998).

Data collected included mortality, myocardial infarction, and reintervention of the LAD. The presence of a myocardial infarction was determined on the basis of electrocardiographic changes, elevated troponin I levels, and creatinine/creatinine myoglobin fractions. These end points were incorporated into an overall assessment of the incidence of major adverse events. Major adverse cardiac events (MACE) were defined as myocardial infarction, reintervention of the LAD, and cardiac-related mortality.

Results

Overall survival was 92.7% (38/41 patients). The 3 deaths were due to noncardiac-related causes: 2 patients died of gas-

TABLE 1. Baseline characteristics

Variable	TECAB group (n = 41)
Age (y)	60.6 ± 8.9
Male sex, No. (%)	36 (88)
Body mass index (kg/m ²)	26.5 ± 0.6
Cardiovascular risk factors, No. (%)	
Current smoking	14 (34)
Hypertension	33 (82)
Diabetes mellitus	12 (30)
Hypercholesterolemia	35 (85)
Previous myocardial infarction	4 (10)
Left ventricular ejection fraction	67.6 ± 1.45
EuroSCORE	2.1 ± 0.1

trointestinal carcinoma and 1 patient died of gastrointestinal bleeding and shock.

Two myocardial infarctions (4.8%) occurred in the follow-up period. One myocardial infarction occurred within the first 6 months after the operation and the other 19 months postoperatively. In both cases the infarct was not located within the region of the bypassed target vessels.

Postoperative angiograms are available from 14 (35%) patients. Reintervention of the LAD was necessary in 5 (12.2%) patients. Two (4.8%) patients required reoperation of the target vessel for graft occlusion. Surgical revascularization was performed by the median sternotomy approach. Two patients received an angioplasty of the LAD (4.8%) owing to significant anastomotic stenosis and in 1 patient owing to a de novo lesion of the distal LAD. Freedom from reintervention of the LAD was 87.8% after a median of 69 months. On the basis of all available postoperative angiography data, the overall patency rate of the LAD was 71.4% (10/14).

Overall freedom from major adverse events for this follow-up was 31 (75.6%) of 41, excluding noncardiac death (34/41, 82.9%; Figure 2). Overall results are displayed in Table 3.

Discussion

With the clinical introduction of the da Vinci system, surgeons are given the opportunity for the first time in history to perform coronary surgery in a closed chest fashion. The following analysis demonstrates that endoscopic revascularization of coronary arteries requires further evaluation.

TABLE 2. Grafted vessels and used conduits

Technique	Grafted vessels and used conduits
TECAB (on pump, n = 8)	LITA-LAD (n = 7) RITA-LAD, LITA-OM (n = 1)
TECAB (off pump, n = 33)	LITA-LAD (n = 30) RITA-LAD, LITA-D (n = 2) RITA-LAD, LITA-OM (n = 1)

TECAB, Totally endoscopic coronary artery bypass; LITA, left internal thoracic artery; LAD, left anterior descending artery; RITA, right internal thoracic artery; OM, obtuse marginal; D, diagonal.

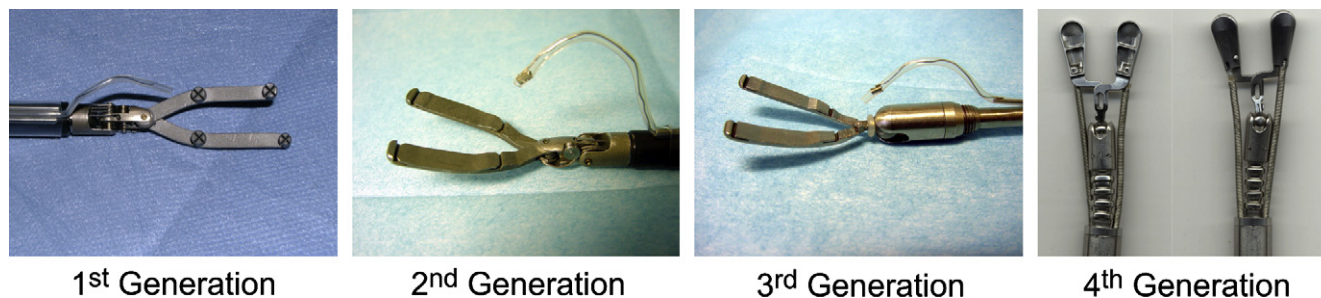


Figure 1. The four stabilizers used in this series. The fourth-generation prototype was able to combine good stabilization through the use of suction with easy maneuverability inside the chest.

The freedom from MACE excluding noncardiac-related death was 82.9%. The small number of patients studied, the lack of angiographic follow-up in this report, and the lack of other long-term clinical follow-up studies after TECAB procedures in the medical literature make it difficult to interpret these results. In 2007, Holzhey, Jacobs, and Mochalski⁵ reported results from a 7-year follow-up study in 1300 patients after minimally invasive direct coronary artery bypass (MIDCAB) where the freedom from MACE was 83%. In 2006, Argenziano, Katz, and Bonatti⁴ reported from a multicenter study on the safety and efficacy of the da Vinci system. In this study, patients underwent a robotic TECAB procedure on-pump. There was no mortality and low morbidity. Three-month angiography, performed in 76 patients, revealed significant anastomotic stenoses (>50%) or occlusions in 6 patients. Overall freedom from reintervention or angiographic failure was 91%.

Up to now, endoscopic revascularization on the beating heart has not translated into a routine procedure within the past 6 years, although significant progress in the technical aspects of the procedure have certainly been made.

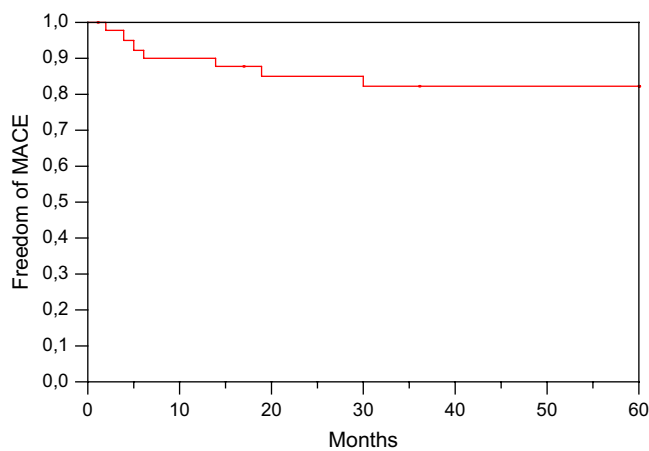


Figure 2. Freedom of cardiac related major adverse events (82.9%) after TECAB.

The need for high-quality outcomes in conjunction with the use of innovative concepts such as robot-assisted surgery will continue to require a significant technologic and intellectual investment to ensure reproducibility of such a complex procedure.

With the rapid evolution of surgical techniques and technologies, the optimal treatment of isolated LAD disease remains extensively debated. Durability and invasiveness of the surgical approach have to be balanced with the relatively less invasive percutaneous treatment, which is often associated with the need for repeat revascularization procedures.⁶

The main focus of any bypass procedure, regardless of the technique used, should be on the quality of the coronary anastomosis. In 2003, Jacobs and associates⁷ presented data describing limitations of telemanipulators such as incomplete motion tracking, delays in tracking, and information tracking. These limitations are likely to negatively affect the quality of an anastomosis, particularly in beating-heart surgery. Surprisingly, in our cohort no significant differences concerning the outcome of on- and off-pump operations could be detected. This might be due to the small number of patients.

TABLE 3. Clinical follow-up results after totally endoscopic coronary artery bypass surgery in a median of 69 ± 7.4 months

End point	TECAB (n = 41)
Death, No. (%)	3 (7.3)
Cardiac	0
Noncardiac	3 (7.3)
Myocardial infarction [no.] (%)	2 (4.8)
<6 mo	1 (2.4)
>6 mo	1 (2.4)
Myocardial infarction and cardiac death, No. (%)	2 (4.8)
Repeated revascularization of the target vessel, No. (%)	5 (12.2)
<6 mo	3 (7.3)
>6 mo	2 (4.8)
Any major adverse event, No. (%)	10 (24.4)

TECAB, Totally endoscopic coronary artery bypass.

ACD

Progress in many of these areas has resulted in much lower conversion rates in later series.⁴ However, to meet the high standards of coronary revascularization, the anastomotic technique should be adjusted to meet the needs of intrathoracic limited space surgery.

In a review of modern anastomotic technology, Carrel⁸ correctly stated that the surgical limitations of the minimally invasive revascularization procedure are related to the inability to perform a conventional hand-sewn coronary anastomosis. He mentioned that there is an urgent need to define the performance objectives of such systems as well as the general criteria for proper and comparable evaluation and validation of different systems in animal models and subsequently in controlled prospective clinical studies.

In 2005 our group⁹ published the results from the pivotal clinical trial using the Cardica C-Port distal anastomosis system (Cardica Inc, Redwood City, Calif). Despite the use of this novel device in often small coronary targets with inferior runoff, the discharge and 6-month angiographic patency results were found to be superior to historical data from the published literature on vein graft patency using conventional hand-sewn techniques. We believe this technology offers a lot of promise for resurgence in TECAB.

Besides anastomotic technology and refinements in stabilization systems, further improvements in technology will be needed. Target vessel identification can be challenging in some patients.¹⁰ Bonatti and associates¹¹ summarized technical difficulties their group has encountered in TECAB procedures. These included difficulties with port hole placement, port hole bleeding, left internal thoracic artery damage during harvesting, epimyocardial lesions during target vessel preparation, problems with the anastomoses, and, in patients undergoing on-pump operations, technical difficulties with cannula and occlusion balloon placement. It is therefore safe to say that intense technologic and procedure-related development will be necessary to reduce the rate of undesirable events and to significantly improve the ease of use.

Currently, TECAB procedures add significantly to the overall procedure costs. This has also been true for the introduction of radically different procedures such as laparoscopic and thoracoscopic interventions. Although initially this may appear prohibitive, in the latter two examples it has not hindered a change in operative standards, and with time and sufficient procedural volume, the costs tend to come down and can often be justified by a reduction in hospital stay, patient morbidity, and a dramatic decrease in invasiveness. We therefore believe it would be premature to discard the development of TECAB procedures at this time on the basis of current health care economics.

Conclusions

Since its introduction in 1999, the TECAB approach to LAD revascularization is still restricted to a few specialized cen-

ters. With this kind of history, TECAB procedures cannot be considered novel, and overall the adoption of this technology has been disappointing and slow for coronary surgery. Widespread adoption is most certainly hindered by the technical challenges associated with this complex procedure. This is especially true with respect to the creation of the vascular anastomosis in a closed chest setting. These challenges, however, are inherent to any novel, disruptive therapy and have been overcome in comparable interventions such as arthroscopic or laparoscopic surgery.

We strongly believe that as cardiac surgeons we have a mandate to continue to refine our technique with the end goal of developing a standard on- or off-pump TECAB procedure for routine use in patients with isolated high-grade LAD lesions. The combination of the excellent coronary artery bypass graft outcomes with a truly less invasive procedure is clearly beneficial to patients.

Limitations of this study include the lack of angiographic patency assessment in the majority of the patients studied. The small number of patients also limits the final conclusions that can be drawn from this experience.

The challenge will be how to refine the technique and accelerate the learning without compromising short- and long-term outcomes. The clinical outcomes in these procedures need to be comparable with those obtained after other minimally invasive surgical revascularization strategies for isolated LAD lesions^{4,5} to justify further exploration of this endoscopic form of therapy. However, there is significant room for improvement, and we believe further technical developments, such as anastomotic devices, are mandatory to achieve the patency and morbidity outcomes we have become accustomed to obtaining after the standard sternotomy approaches.

Limitations

A number of limitations in this study need to be taken into account. The TECAB technique was performed with a first-generation telemanipulator.

The implementation of a completely new device, technique, and surgical approach was certainly associated with a learning curve in all steps of the procedure, especially with regard to the endoscopic creation of the vascular anastomosis, which included learning how to identify, dissect, and control the target vessel.

Commercially available endoscopic stabilizers had not yet been developed; therefore, the quality of the anastomoses was probably negatively affected by the use of these early endostabilizer prototypes (Figure 1). The procedure was evolving during this initial series, resulting in a large number of variations in the surgical techniques used.

The data obtained were from a single center; therefore, our technique did not benefit from the knowledge obtained by other centers during the same period. Follow-up obtained in this series was restricted to clinical outcome and did not

include complete long-term angiographic assessment of patency. Finally, the number of patients enrolled was small.

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Discussion

Dr Ralph J. Damiano, Jr (*St. Louis, Mo*). I would like to congratulate Dr Kappert and his colleagues for providing long-term follow-up on this very important cohort of patients and also for their pioneering work in the field.

It is interesting, now, getting on almost 10 years since the first robotic coronary procedures were done in both Europe and the United States, that we can begin to look at some long-term follow-up. It also is a bit humbling to look at how small the series have remained. This probably is the biggest word of caution before people go out and embark on these programs themselves.

I have a number of questions. I will ask them one at a time.

First, robotic technology was introduced to enhance dexterity. This was the basic premise for the adoption of these very expensive systems. However, it was very clearly shown in an experimental model by Dr Volkmar Falk several years ago, which I am sure you are aware of, that robotic instrumentation actually is a lot worse than doing it by hand in the beating-heart environment; that is, the error rate with robotics was significantly higher than with manual instrumentation, so actually it reduced dexterity in this environment.

Also, in the clinical trial of the ZEUS system (Computer Motion, Inc, Goleta, Calif), which was not as sophisticated a system as the

Intuitive da Vinci system, the off-pump patency was significantly worse.

You had two groups of patients. In the first group the heart was arrested and in the second it was beating. If you separated the groups and told us what the major adverse event rate or target revascularization rate was just on your beating-heart group, can you separate the 8 arrested-heart patients from the beating-heart ones? I think that is an important differentiation for this technology. These systems do not seem to respond well when there is any type of motion. Have you looked at these groups separately?

Dr Kappert. I think Dr Cichon can answer this question. He did nearly 100% of the procedures by himself.

Dr Romuald Cichon (*Dresden, Germany*). Thank you very much. I am the senior partner of my friend.

The first part of the question concerned dexterity. As you know, we have augmentation of almost 10 times using this kind of a robotic. We have a filter to mask the tremor. Thus I do not believe that with good stabilization dexterity will be lessened with this system. However, the crucial aspect of this answer would be good stability and good stabilization of the cardiac wall.

Your second question concerned off-pump versus on-pump techniques. Of course, we started with the on-pump technique in the very early days. But somehow, aiming to the goal of minimally invasive cardiac surgery and going back to the on-pump era felt somehow unfair. After we achieved a good sequence to the procedure, which allowed us, in a considerable time, to perform the whole operation, we switched to the off-pump technique. There was quite a rocky ride. At that time, we had only the No. 4 prototype of the stabilizer that we were developing. Now we have the No. 7 prototype, as I recall. This is the kind of development that we got.

Basically, that was the worst part of the story. With augmentation of up to 10 times, even a very small movement seems like an earthquake.

Dr Damiano. I guess I still did not get an answer to my question. If you looked at the stenotic vessels and the ones that needed revascularization, were they all in the beating-heart group? If so, your denominator then is much less and then your rate of major adverse events may be much higher.

My question is, were the adverse events clustered in the beating-heart population? Both experimental data would suggest it may be worse, as did the initial clinical work with the ZEUS system that has been published previously. If you looked at it separately, what did you see?

Dr Cichon. Unfortunately, we did not see any difference. In both of the groups, we had one graft that failed, which probably was related to poor handling in the preparation of both of the thoracic arteries. Again, this series of 8 cases and then 30 cases is too small to allow us to very distinctly differentiate those complications. The only difference that you have seen was the progressive coronary disease in the group of off-pump operations, but in a natural way there were simply more patients involved.

Dr Damiano. If we had catheterization data on everyone, we really could get a good idea of patency. Unfortunately, few patients in this trial had a postoperative catheterization. But you actually do have catheterization data on, I would estimate, at least 7 of the patients, because those are the patients who had either a myocardial infarction or target vessel revascularization. If you just looked at the catheterization data you have, what would be the patency rate of that small cohort?

Dr Kappert. What would it be?

Dr Damiano. And stenosis. You are obviously picking a selected group. But you do have catheterization data on a part of this group, so I was surprised not to see that presented.

Dr Cichon. We treated those patients as we did any other patients with coronary disease treated in our clinic. We did not perform coronary angiography in all the patients. Our practice is to screen a patient for angiography if there is an ischemic event. Otherwise, we do not do angiography. Thus the 7 patients whom we have seen are the patients who had a problem with ischemia. In most cases, angiography was done more than 6 months after the operation. Those are the data that were presented.

Dr Damiano. It just was unclear. You did more than one graft on some of those patients, so I was just wondering whether you had the total number of grafts that were visualized by angiography at late follow-up and how many of those had either stenosis or occlusion. This would be another interesting number. It is very possible in your group that you may have had a number of asymptomatic occlusions that you would have been unaware of had the patients not come back for follow-up.

Dr Cichon. Well, of course, we can exclude it; however, angiography is not the only parameter of cardiac ischemia or the diagnosis of cardiac ischemia. We have other parameters that we used as our routine.

Dr Damiano. I did not see those data. Are you saying that all the patients had routine stress tests?

Dr Cichon. Well, of course, they had echocardiography, electrocardiography, and enzyme monitoring. All of those patients were monitored in the standard manner used in every patient in our clinic.

Dr Damiano. I guess I'm just trying to get a better feel for what was actually the patency rate in this cohort.

I would like to finish with a question. This is a very highly selected group, 1% of your volume. It is all patients with principally single-vessel disease, and I am sure you mentioned that you took even the best of that group. This was a lower risk group than your normal cohort, and I assume they all had an excellent-quality LAD or you would not have put them in this initial trial. With this in mind, I would like to emphasize a word of caution. The reintervention rate of 12% at 5 years in this type of a cohort, particularly since there was not good angiographic follow-up, is not great. I do agree with your final comment that these procedures should be approached cautiously. This is hardly being done anywhere in the world, but certainly if it is being done, it should be done in very highly specialized centers that have tremendous dedication, as you have had, to try to develop the technology. My own impression is that there are very inherent limitations of robotics. The present robotic systems in a beating-heart environment actually decrease your dexterity.

Besides anastomotic devices, which I agree would be an improvement, what else could be enhanced with these robotic systems that could improve the results in the beating-heart situation?

Dr Kappert. I believe the first (and very important) thing that we missed from that day, basically up to today, is a sufficient number and quality of synergic instrumentation. At that time we started

with 9 instruments suitable for the robotic system. Today we have, I believe, 40, and we are not done by far with the instrumentation. That is probably the most important thing that we have to improve. I see an immense area for industry to develop. However, I know it is very difficult at that time.

On the other hand, the overall improvement of the system, with a fourth arm right now, is also increasing the ability to use this in a much safer manner.

Dr Valavanur Subramanian (*New York, NY*). I have three points of not just caution, but help, from the days of MIDCAB. Very early on, we showed that a good stabilization equals a good patency. We have graded the stabilization as A, B, and C and have looked at that. By that I mean not only the mechanical stabilization but also the internal stabilization of the artery that you are going to sew. We presented information at the American Heart Association meeting in 1996 about the shunted group and nonshunted group and a MIDCAB, and there is tremendous difference.

Second, anybody who does beating-heart surgery through a minimally invasive approach must have a controlled angiogram. By that I mean I do not think you should have just a fixed, given patency. We again did some work on looking at minimum luminal diameter, waist stenosis, toe stenosis, and heel stenosis, just like interventional cardiologists will do, because it did enhance our technical performance to do a better MIDCAB operation. Thus I think it is not enough to just have patency.

We also have some indication that it correlates very well with a long-term patency late rate in our own group and the MIDCAB group. Therefore, I would say that if you are going to do closed chest heart surgery you must have a controlled angiogram in these patients, of some period, and evaluate it very carefully, not just the patency. I think you should look in the details of the anastomotic milieu, the stenosis, where the stenosis is, and the luminal diameter, just as interventional cardiologists do, who have perfected their staying technique, to a point where they do not believe that 30% is enough. It is important for us to rigorously look at these techniques to have good results. Unless you do that, you will not learn what the problems are with TECAB and will not be able to improve.

Did you use a shunt in some of these patients? It does help you to place the precise stitches. We are doing suture technique with the TECAB. Does it help you to put a shunt in so that you can control your anastomotic milieu?

Dr Cichon. Yes, we did use a shunt in some of those patients.

Dr Subramanian. Did you see a difference?

Dr Cichon. Not too much, because the main problem with the suturing was still good stabilization. It did help us. However, the mean anastomotic time was about 14 minutes, so we did not think that we were going to do too much damage to the vessel.

Dr Vaughn A. Starnes (*Los Angeles, Calif*). I have just one additional comment. Having worked with the robot a fair amount, I think that the coupling devices will help with tactile feedback and handling the tissues, handling the sutures. Sometimes I think we create stenosis on the suture line by trying to use general methods that we normally use with hand dexterity and I just do not think are applicable with the robotic system.