

Clinical Investigation: Endoscopic Coronary Artery Bypass Grafting with Robotic Assistance

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ABSTRACT

Background: The current study reviews clinical feasibility experiences evaluating safety and efficacy of using robotic assistance to create a left internal mammary artery to left anterior descending artery (LIMA-to-LAD) anastomosis.

Methods: Between August and November 1999, 9 patients (aged 54-73 years) underwent robotically assisted endoscopic coronary artery bypass grafting (E-CABG) after institutional review board approval and informed consent were obtained. The robotics were transthoracically introduced in the fifth and sixth intercostal spaces. The LIMA-to-LAD anastomoses were endoscopically constructed with robotic assistance, and patency was assessed by flow measurement.

Results: Each anastomosis was performed robotically, without necessity for intraoperative intervention with traditional techniques. Robotic anastomosis times averaged 29.05 minutes. The robotic system added on average 41.28 minutes to the procedure. LIMA flows prior to anastomoses measured from 11.2 to 29.2 mL/min. LIMA flow measurements following anastomoses averaged 42.07 mL/min. There were no deaths or perioperative myocardial infarctions.

Conclusions: Although E-CABG is an exhaustive and technically demanding procedure, it is feasible for a computer-enhanced robotic telemanipulation system to safely and effectively provide substantial assistance to the surgeon completing a thoracoscopic coronary anastomosis.

INTRODUCTION

The impressive achievements associated with conventional coronary artery bypass grafting (CABG) surgery are largely attributable to an excellent surgical "platform" of factors that combine to facilitate precise anastomotic suturing—full sternotomy and total exposure of the heart, cardiopulmonary bypass support, myocardial protection, and a bloodless and motionless surgical field. Both port-access and minimally invasive direct coronary artery bypass (MIDCAB) procedures present far greater technical challenges, which have been

shown to occasionally surpass the skills of even the most expert surgeons [Amunson 1997].

Of all the technical challenges accompanying coronary artery bypass surgery, the most important is the construction and performance of a perfect anastomosis. Moreover, revascularization success ultimately rests on a technically superior graft that supplies adequate blood flow to the ischemic area of the heart for an extended period of time [Amunson 1997].

Cardiac surgery remains the largest surgical discipline that still employs a highly invasive approach. The need for invasive surgery is primarily due to the difficulty encountered in performing the precise and highly dexterous motions required to endoscopically suture the tiny coronary vessels on the heart with hand-held instruments [Amunson 1997]. Endoscopically sutured anastomoses have been difficult and time-consuming to perform because of the length, accentuated hand tremor, and fixed pivot point of standard endoscopic instrumentation [Mack 1997, Stephenson 1998, Damiano 2000]. Prolonged intracorporeal microsuturing procedures provide a significant challenge for surgeons. Although endoscopic magnification enhances visual perception, the optically magnified hand tremor forces the surgeon to slow down in order to compensate for diminished dexterity. Longer operative time leads to surgeon fatigue, which further amplifies the hand tremor, completing a malicious circle [Soper 1992, Cushieri 1995, Falcone 1999].

Recently, technological developments, such as robotics, have been developed to address the difficulties of endoscopic suturing [Borst 1997, Garcia-Ruiz 1997, Mack 1997, Shennib 1998, Stephenson 1998, Damiano 2000]. Robotic assistance for endoscopic surgery has dramatically improved in the last 5 years [Gagner 1994, Kavoussi 1994, Sackier 1994, Begin 1995, Kavoussi 1995, Garcia-Ruiz 1997, Falcone 1999, Moore 1996]. The most recent advances in robotic technology have made it possible to simultaneously manipulate the endoscope and various endoscopic instruments, enabling full robotic assistance to perform several aspects of the surgical procedure [Falcone 1999].

The following clinical investigation uses one such robotic system—the ZEUS Robotic Surgical System (Computer Motion, Goleta, CA, USA). ZEUS consists of 3 robotic arms controlled by the surgeon, computer controllers, and a surgeon console (Figures 1 and 2). One robotic arm positions an endoscope and camera assembly in response to simple voice commands given by the surgeon. Working behind the ergonomic console, the surgeon operates handles to input

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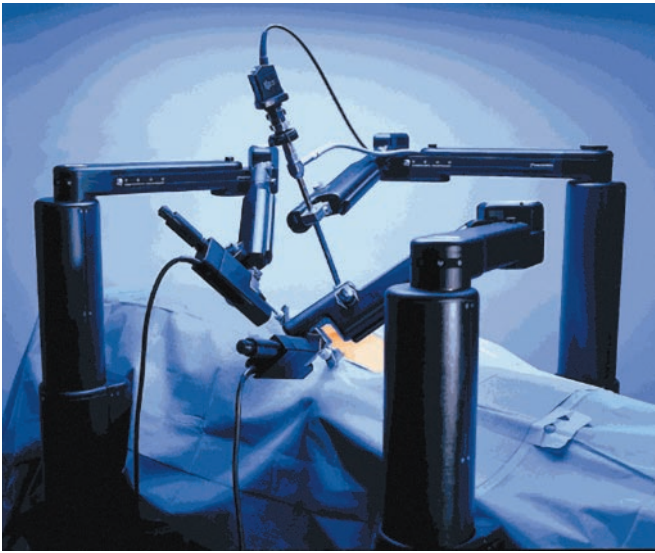


Figure 1. Digital image of the ZEUS Robotic Surgical System arms attached to the standard operating room table rails and positioned around the patient.

movements that are scaled and translated by the computer onto the instruments.

With the computer dampening the surgeon's hand tremor and scaling the surgeon's movements, robotics may provide the precision necessary to perform endoscopic coronary anastomoses [Mack 1997]. We believe that robotic assistance will enable fully endoscopic CABG surgery. As a result, these new minimally invasive surgery procedures will provide significant patient benefits such as decreased pain and trauma, shorter hospital stays and convalescent periods, and lessened cosmetic concerns. Furthermore, an increase in minimally invasive procedures will result in lower overall health care costs [Amunson 1997].

MATERIALS AND METHODS

This clinical investigation is our center's contribution to a US Food and Drug Administration (FDA)-approved study involving 30 patients at 3 centers. The primary objective of this investigation was to evaluate the safety and efficacy of the ZEUS Robotic Surgical System when used to perform CABG. The study protocol dictated that the ZEUS system be used only for LIMA-to-LAD anastomosis on nonbeating hearts. Except for the LAD, bypass of diseased vessels was performed using conventional hand-held instrumentation.

Patients of both sexes were enrolled if they met the inclusion criteria outlined below:

- Elective or urgent CABG surgery
- First-time CABG procedure
- Critical lesions of the LAD (>50% stenosis)

Patients meeting the inclusion criteria were not included in the study if they met any of the following exclusion criteria:

- Ejection fraction of <40%
- Severe ventricular arrhythmias

- Coagulation disorder
- Severe noncardiac conditions with poor prognosis
- Inability to follow the protocol requirements
- Myocardial infarction within 7 days prior to the procedure
- Chronic renal insufficiency
- Donor or target vessels <1.5 mm in size
- Calcified or diffuse coronary disease in the LAD
- Concomitant surgery
- Weight >1.5 times ideal body weight
- Previous thoracic surgery
- Age >80 years
- Preoperative intraaortic balloon pump
- Participation in any other investigational device or drug study

Following institutional review board approval, 11 patients were enrolled in and consented to this study. Two patients were intraoperatively excluded because of inadequate donor and target vessel sizes.

The conventional equipment was placed in the room according to the standard open-heart room setup at this institution. Additionally, the robotic arms were attached to the table rails and positioned relative to the patient. The robotic arms were connected to the surgeon console and the system was powered on. The robotic arms were then rotated away from the operative area to allow the surgeon direct access to the patient for the conventional portion of the procedure (Figure 3[©]).

The first 3 patients had traditional open heart surgery, while the heart was placed on cardiopulmonary bypass (CPB) throughout the procedure except for the LIMA-to-LAD anastomosis. This anastomosis was performed with robotic assistance on a nonbeating heart, per the FDA study protocol.



Figure 2. Digital image of the ZEUS Robotic Surgical System surgeon console.

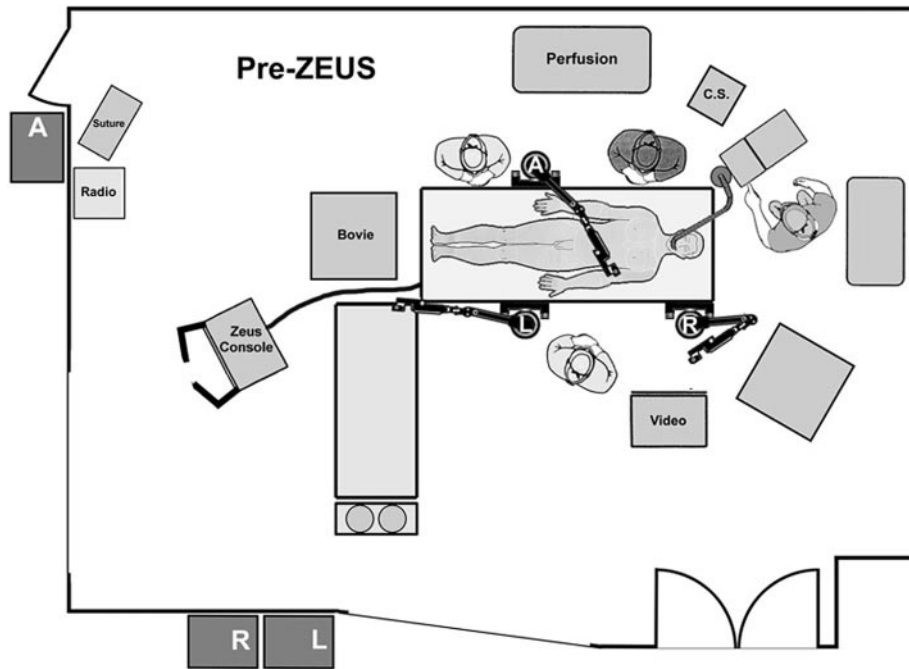


Figure 3. Overhead diagram of the robotic arm placement and orientation prior to surgery. A indicates AESOP endoscope arm; L, left arm; R, right arm.

The last 5 patients, who had multiple vessel coronary disease, underwent a beating/stopped-heart hybrid procedure. Each diseased vessel, except the LAD, was bypassed using conventional hand-held instrumentation. These 5 procedures consisted of an off-pump coronary artery bypass (OPCAB) portion (performed on each vessel, except the LAD) followed by a stopped-heart LIMA-to-LAD anastomosis portion. For one patient with single-vessel coronary disease, an endoscopic LIMA takedown was performed. Because of an intramyocardial LAD, the fully endoscopic approach was abandoned for a minithoracotomy approach. During each of the 9 procedures, the ZEUS portion, as outlined below, followed the conventional CABG or OPCAB methods.

A 5-mm port was inserted in the fifth intercostal space (ICS) at the anterior axillary line (Figure 4). A 5-mm zero-degree Hopkins II #26006AA (Karl Storz, Tuttlingen, Germany) endoscope was placed into the port and positioned by AESOP (Computer Motion), a robotic voice-activated endoscope-positioning system. Light was provided by a Xenon 300 #20133020 (Karl Storz) light source set at 50%. The video image was produced by a Tricam SL NTSC #20222120 (Karl Storz) 3 charge-coupled device camera.

Two additional 5-mm ports were placed in the fifth ICS anterior to the midaxillary line and the sixth intercostal space at the midclavicular line to introduce the ZEUS right and left instruments, respectively (Figure 4). This ideal port-placement strategy was previously determined and verified through our past cadaveric study [Tabaie 1999].

At this point, the ZEUS system was arranged to perform the LIMA-to-LAD anastomosis (Figure 5). The right robotic arm was located on the patient's left side, in line with the top of the head. The left robotic arm was positioned on

the patient's left side, between the pelvis and knee. The endoscope positioning arm was placed on the patient's right side, across the table from the left robotic arm.

The robotic instruments were introduced, and the surgeon moved from the table side to the surgeon's console (Figure 6). From this console, the surgeon's movements were

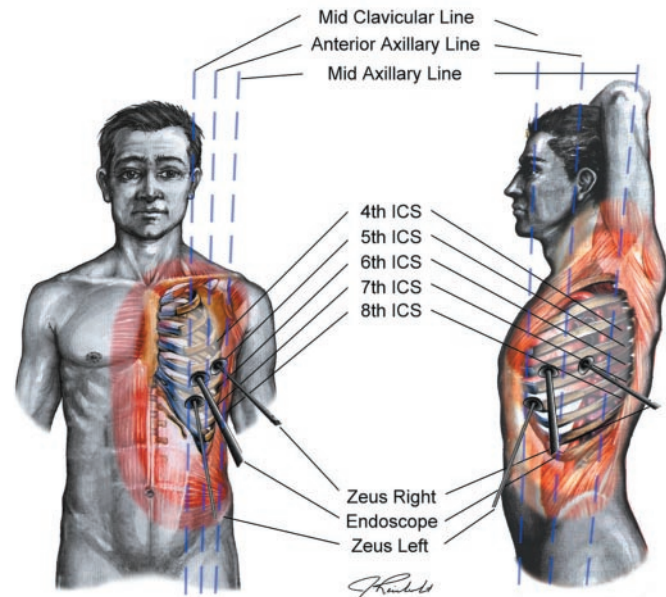


Figure 4. Port placement diagram for the robotically assisted left internal mammary artery to left anterior descending artery (LIMA-to-LAD) anastomoses.

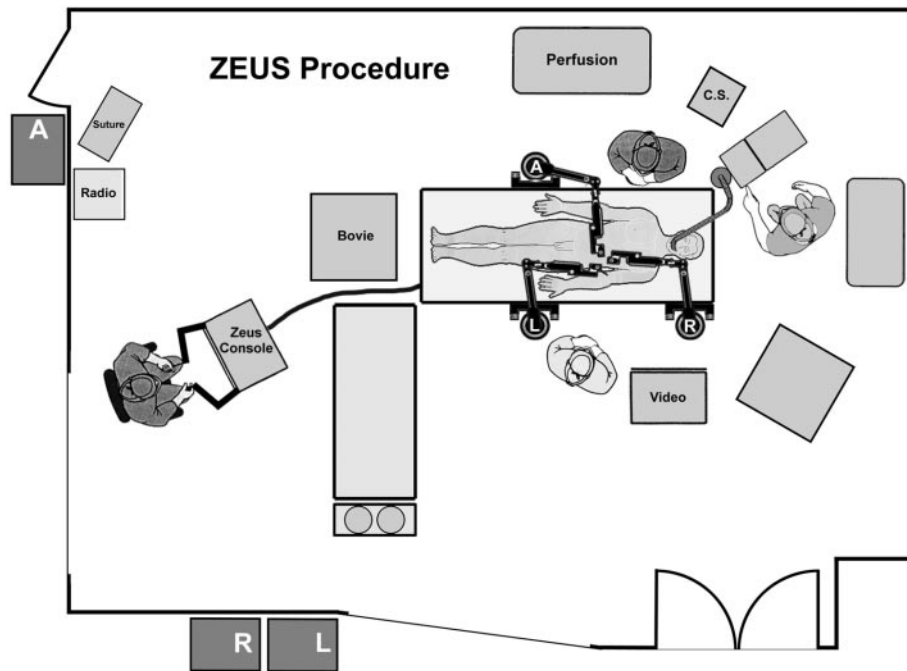


Figure 5. Overhead diagram of the operating room setup for the ZEUS constructed anastomosis portion of the procedure.

electronically translated to the instrument tips in order to complete the anastomosis.

The anastomosis was constructed with 7-cm-long double-armed 7-0 Gore-Tex (expanded polytetrafluoroethylene) (W.L. Gore, Flagstaff, AZ, USA). The assistant, gaining access through the median sternotomy, provided countertraction on the tissue (Figure 7[Ⓢ]).

The surgeon continued down the left side of the arteriotomy, rounding the toe and finishing with the opposite needle down the right side of the arteriotomy. Six square knots were tied at approximately the 4 o'clock position on the anastomosis, where the 2 suture ends met.

Following the robotic anastomosis, an intraoperative ultrasonic transit-time flow measurement was recorded for the LIMA-to-LAD graft. The patient's body temperature was rewarmed and then weaned from the CPB machine. On removal of the robotic instrumentation, the remainder of the procedure followed the choreography of a standard open heart surgery at this institution.

RESULTS

In total, 4 female and 5 male patients underwent robotic surgery. Each of the 9 endoscopic LIMA-to-LAD anastomoses were performed robotically, without the necessity for intraoperative intervention with traditional techniques. The patient ages ranged from 54 to 73 years (average 64.89 ± 6.49). The average height and weight were 174.27 ± 7.72 cm and 86.55 ± 14.98 kg. The ejection fractions spanned 40% to 76% (average, $52.89\% \pm 11.99\%$).

The average robotic anastomosis time was 29.05 ± 6.01 minutes (range, 21.9-42.95 minutes). The total time the

robotic system added to the entire procedure averaged 41.28 ± 5.15 minutes (range, 35.35-52 minutes).

LIMA flows prior to anastomoses measured from 11.20 to 29.20 mL/min (mean, 21.62 ± 7.02 mL/min). LIMA flow measurements following anastomoses averaged 42.07 ± 16.84 mL/min (range, 21.20-66.00 mL/min) (Figure 8[Ⓢ]).

The total number of bypasses performed per case (including robotic, conventional OPCAB, and conventional stopped-heart techniques) averaged 2.89 ± 1.36 vessels, with an average cross-clamp time of 55.54 ± 21.45 minutes (range, 31-74 minutes). The total intensive care unit time per patient ranged from 14.85 to 49.95 hours (average, 23.01 ± 10.36 hours). The



Figure 6. Digital image of surgeon operating behind the surgeon's console.



Figure 7. Digital image of robotic arm configuration, port placement strategy, and assistant's access during a robotic surgery.

total hospital stay averaged 6.75 ± 1.53 days (range, 4.67-8.00 days). There were no deaths, perioperative myocardial infarctions, or postoperative explorations for bleeding.

The robotic arms were found to allow versatility in their placement on the table rails. The robotic arm placement strategies (Figure 5) were used to coincide with the above-port placement strategies (Figure 4). We did not encounter any mechanical failures related to the robotic system.

COMMENT

E-CABG is a long, exhaustive, and difficult procedure. Fifteen years ago, general surgeons were describing the laparoscopic cholecystectomy procedure in this same way. Initial attempts at a totally endoscopic approach to cardiac surgery have been abandoned in favor of a minithoracotomy [Stephenson 1998, Moore 1996, Sackier 1994]. The realization of the final goal of a fully endoscopic coronary artery

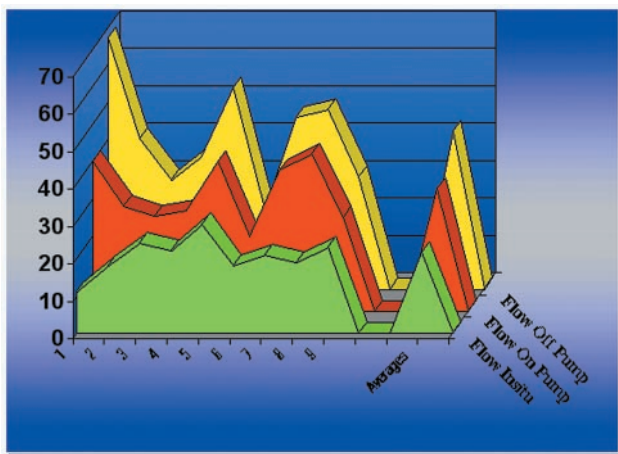


Figure 8. Chart displaying the flow values (mL/min) for each of our 9 patients and the average flows. The average flow in situ was 21.62; the average flow on cardiopulmonary bypass was 32.60; and the average flow after weaning from bypass was 42.07.

bypass has not yet been achieved and must wait until cardiac instrumentation technology advances and overcomes the technical challenges and limitations of today [Stephenson 1998].

Medical robotics have been manufactured and in use for some time but have only recently been introduced to the cardiac community. The robotic system does not replace a surgeon; however, it does significantly enhance a surgeon's skills and dexterity. The robotic system provides substantial assistance in performing extensive endoscopic procedures, such as electronic elimination of natural hand tremor, scaling down of the surgeon's instrument movements, and robotic positioning of visualization of the magnified surgical field. Such benefits, in addition to comfortable seating in an ergonomically designed chair, result in reduced fatigue, precise surgical movements, added stability, and surgeon comfort.

The current study demonstrates that an E-CABG procedure with robotic assistance is safe and efficacious. Proper port placement setup plays an essential role in extensive endoscopic suturing procedures [Cushieri 1995]. Moreover, the robotic arm placement setup is paramount to reducing the degree of difficulty and ensuring the success of the procedure.

The present study provides a foundation for the determination that robotic instrumentation enables endoscopic coronary artery bypass procedures. It is necessary to expand on the current study and related studies, performed in Munich, Germany [Reichenspurner 1999], and Hershey, Pennsylvania [Damiano 2000], with future clinical trials to determine the role robotic assistance will have in tomorrow's cardiac procedures.

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