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Endoscopic Coronary Artery Bypass Grafting on the Beating Heart Using a Computer Enhanced Telemanipulation System

Dr. Falk

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ABSTRACT

Objective: To develop a technique for computer enhanced endoscopic arterial bypass grafting on the beating heart in an experimental canine model.

Methods: Mongrel dogs (30-35 kg) were used. After single lung ventilation of the right lung was initiated the dogs were placed to the right. The videoscope and the end-effectors of the da Vinci™ telemanipulation system (Intuitive Surgical, Mountain View, CA) were introduced through three ports. Surgery was performed remotely from the console (motion scaling 3:1). After harvesting of the internal thoracic artery (ITA) and preparation of its distal end, the Endostab™, a newly developed endoscopic stabilizer was introduced through an additional port. The anterior wall of the heart was stabilized and the collateral branch (RC) of the left anterior descending artery (LAD) was ligated proximally and distally. The arteriotomy was made and the ITA-graft anastomosed to the RC. The animals were sacrificed and the grafts were checked for patency using bench angiography.

Results: In two of five dogs total endoscopic beating heart bypass grafting, including ITA harvest, stabilization, arteriotomy and performance of the anastomosis, was successfully performed using computer enhanced technology and a new endoscopic stabilizer. In two dogs the procedure was completed with femoro-femoral cardiopulmonary bypass (CPB) support on the beating or fibrillating heart, respectively. One dog expired due to VT. Hemodynamically, endoscopic stabilization was well tolerated. All four grafts were patent despite a target vessel diameter of less than 1 mm.

Conclusion: The endoscopic stabilizer can sufficiently immobilize the heart to enable endoscopic beating heart coronary artery bypass grafting by means of a computer controlled instrumentation system.

INTRODUCTION

Telemanipulation systems have been introduced to cardiac surgery to enable endoscopic coronary artery bypass grafting. Using computer-controlled instruments, several limitations of conventional endoscopic instruments that have prevented endoscopic bypass grafting thus far have been overcome. Experimental studies have demonstrated that different types of telemanipulation systems enable endoscopic coronary anastomoses to be performed with high precision and equal quality when compared to conventional techniques[Stephenson 1998a, Ducko 1999, Falk 1999a]. The feasibility of closed chest bypass grafting of the left internal thoracic artery [ITA] to the left anterior descending artery (LAD) has been shown in ongoing clinical trials [Falk 1999b, Loulmet 1999, Mohr 1999a]. However, due to the lack of endoscopic stabilization devices closed chest bypass grafting has been performed only with the use of cardiopulmonary bypass (CPB) and cardioplegic arrest using the Port-Access™ technique [Falk 1999c, Loulmet 1999]. Although a totally endoscopic approach is appealing, the use of CPB for an operation that could be easily performed on the beating heart through a small anterior thoracotomy minimizes the potential benefit for the patient. The aim of this study is to develop an endoscopic stabilizer that will enable local immobilization of

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the anterior wall of the left ventricle through a trocar, thereby allowing for closed chest beating heart coronary artery bypass grafting. The feasibility of such an approach was tested in a live canine model.

MATERIALS AND METHODS

Stabilizer

The requirements for an endoscopic stabilizer are numerous. First, the heart has to be sufficiently immobilized. It has to be operable through a trocar and be externally fixable. It should be reusable and easy to sterilize. Together with the German Research Center in Karlsruhe a device that fulfills these requirements was developed. The Endostab™ (patent pending) is a reusable stabilization device of 10 mm in diameter. The shaft can be inserted through a 12 mm port. By means of an external screw two preshaped stabilization pads made of Nitinol unfold to finally open perpendicular to the shaft and parallel to each other, leaving 2 cm of immobilized myocardium between the pads. For external fixation of the device, an Octopus® passive articulating arm was used.

Telemanipulation system

The da Vinci™ system (Intuitive Surgical, Mountain View, CA) consists of a master console that connects to a surgical "manipulator" with two instrument arms and a central arm to guide the videoscope. At the master console the surgeon works on two "master" handles that trigger highly sensitive motion sensors. Motions from the handles are translated to the tip of the instruments (end-effectors) at a remote location. The system works with fixed remote center kinematics that minimizes side loads on the body wall and thus trauma at the point of entry. Joint motion is provided by electronic actuators (DC servo motors). The surgical manipulators have three degrees of freedom (pitch, yaw and insertion) and provide motion coupling to the end-effectors — exchangeable surgical instruments that provide another three degrees of freedom. By means of a mechanical wrist a total of six degrees of freedom plus tool actuation is provided at the tip of the instrument allowing for free motion in three dimension. Motion scaling, tremor filtering and the possibility of disconnecting the slave from the master enhance the precision, and provide optimal hand-eye alignment and favorable ergonomics. A high-resolution 3D-videoscope [two 3-chip CCD cameras] is controlled by the footswitch that locks the slave tool manipulators in place and gives the operator control of the camera through the master manipulators. This method of controlling the endoscope provides easy and fast positioning of target anatomy in the image while keeping the slave tool tips in the operator's view. A detailed description of the system is provided elsewhere [Shennib 1998, Carpentier 1999, Falk 1999c, Falk 1999d, Falk 1999e, Shennib 1999].

Animal Instrumentation

Five mongrel dogs at a weight of 30 to 35 kg were used. For premedication, proprionylpromazine (5 mg/kg IM), levomethadonchloride (0.5 mg/kg IM) and atropine (0.05 mg/kg IM) were given. Orotracheal intubation using a 9.5 mm single lumen tube was performed when anesthesia was sufficient for direct visualization of the larynx. The left bronchus was blocked, using a bronchial blocker placed with bronchoscopic guidance. For maintenance of anesthesia isoflurane 1-1.5% in oxygen and fentanyl infusion (0.02 mg/kg/h) were given. For relaxation, pancuronium (0.02 mg/kg) was applied every hour. An arterial line was placed in the right cubital artery. A triple lumen central venous line was placed in the right jugular vein. The animals were placed to the right. Monitoring included ECG, direct arterial blood pressure, and central venous pressure (CVP). All pressure measurements and ECG signals were digitized and recorded every 5 minutes for 10 seconds. Intrathoracic pressure (ITP) was continuously measured. Serial arterial blood gases were taken, and end-tidal CO_2 and SaO_2 were measured. Intermittent positive pressure ventilation (IPPV) was used. Minute ventilation settings during one lung ventilation (right lung) depended on blood gases and the cardiovascular effects of IPPV (10-13 ml/kg, ventilation rate 35-40/min). The normal peak inspiratory pressure was kept at 35 mm Hg. Full electrolyte solution was given at a maintenance dose of 10 ml/kg/hr. Before entering the chest the animals were fluid-loaded with a 10-20 ml/kg bolus of Lactated Ringers solution (depending on blood pressure and CVP/ITP). For inotropic support, dopamine and ephedrine infusions were used. For treatment of arrhythmias, lidocaine was administered. The right groin was dissected and the femoral artery and vein were encircled with a vascular tape in case cannulation for CPB was required.

Surgery

After the left lung was deflated a 12 mm trocar was inserted at the fifth intercostal space (ICS) and CO_2 insufflation administered to an intrathoracic pressure of 10 mm Hg or lower as tolerated. A 30° scope, angled upward, was inserted. Two instrument ports were created at the third and seventh ICS and the da Vinci™ system was placed.

Figure 1. Intraoperative setup. The da Vinci™ system is placed from the right. The Endostab™ is placed through a fourth trocar.

Figure 2. Endoscopic view during ITA take down

From this point onward, the surgical procedure was performed remotely from the console (see Figure 1 ◎). The LIMA was harvested as a pedicle, using low energy cautery (see Figure 2 ◎). The distal end was clipped after administration of 5000 units of intravenous heparin. An angled vascular clamp was placed proximally to temporarily occlude the artery. While still attached by concomitant veins and fascia, the distal end of the ITA was then skeletonized, cut and prepared for the anastomosis in situ (see Movie ◎). This technique is helpful since it provides some countertraction that facilitates working on the distal end. The pericardium was then opened with cautery, and the LAD and its side branches were identified. The endoscope was switched to a 0° scope and the Endostab™ was inserted through a fourth trocar (see Figure 3 ◎). After sufficient immobilization was achieved (see Figure 4 ◎), the LIMA was detached, approximated to the anastomotic site and fixed to the epicardium with a 6-0 Prolene™ stay suture. The second collateral branch of the LAD was occluded both proximal and distal to the site of the anastomosis by encircling the vessel with a 4-0 Prolene™ suture. After blunt dissection of the coronary artery, an arteriotomy was made with a sharp blade and enlarged with Potts-Smith

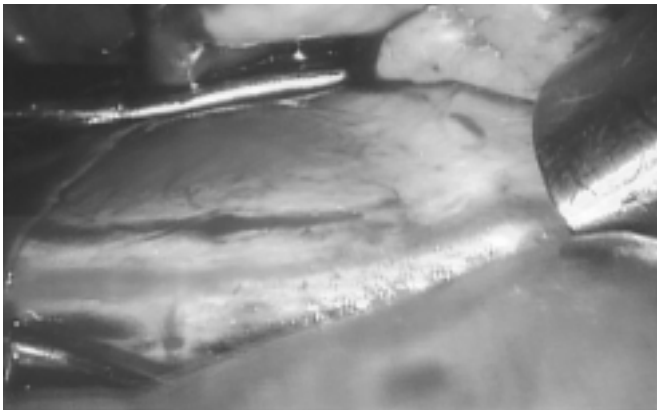

Figure 4. Endostab in place.

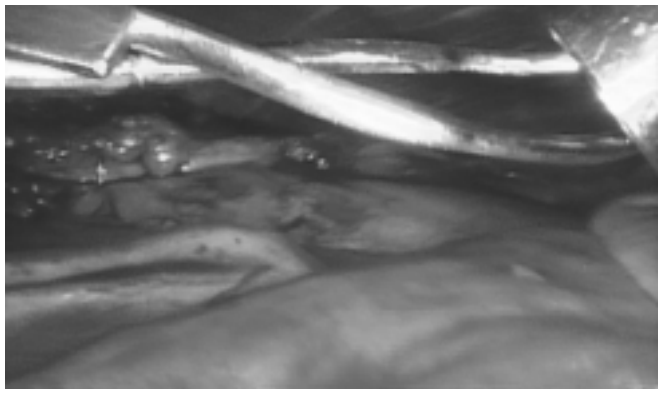

Figure 3. Insertion of the Endostab™, an expandable pressure stabilizer. By means of an external screw, two Nitinol pads unfold in the chest.

scissors (Sklar Instruments, West Chester, PA). A conventional end-to-side anastomosis was created (see Movie ◎) using an 8-0 Prolene™ running suture (double armed, 7 cm of length, Ethicon, Norderstädt, Germany) as described previously [Falk 1999a]. The distal snare was opened, the vascular clamp was removed from the ITA, and the Endostab™ withdrawn (see Movie ◎). A lateral thoracotomy was made to inspect the result in situ and then to harvest the heart. Bench angiography of the graft was performed by injecting radiographic contrast into the proximal end of the ITA.

All animals received humane care in compliance with the "Principles of Laboratory Animal Care" formulated by the National Society of Medical Research and the "Guide for the Care and Use of Laboratory Animals" prepared by the Institute of Laboratory Animal resources and published by the National Institutes of Health (NIH Publication No. 85-23, revised 1985).

RESULTS

In two of the five dogs, totally endoscopic beating heart bypass grafting (including ITA harvest, stabilization, arteriotomy and performance of the anastomosis) was successfully performed using computer enhanced technology and a new endoscopic stabilizer (see Figure 4 ◎). Three dogs went into ventricular fibrillation (one during ITA harvest, one during pericardotomy, and one during application of the stabilization device). After successful resuscitation two dogs were put on femoro-femoral CPB and the procedure was completed on the fibrillating heart (one dog) or on the beating heart (one dog). One dog expired before CPB could be initiated and the procedure was therefore not completed. An example of the hemodynamic changes induced by CO_2 insufflation and application of the Endostab™ is given in (Figure 5 ◎) [Dog 5]. CO_2 insufflation led to a decrease in arterial pressures while central venous pressure increased. During stabilization, mean arterial pressure further decreased. Using moderate volume substitution and low dose dopamine, these hemodynamic alterations were well controlled. Procedural times are shown in (Table 1 ◎). In two dogs the procedure could be

Table 1. Procedural times. BH = beating heart; FH = fibrillating heart; CPB = cardiopulmonary bypass; ITA = internal thoracic artery; NA = not applicable

No	Procedure completed	No of ports	Surgery [min]	ITA [min]	Arteriotomy [min]	Anastomosis [min]	Patency [ex vivo angio]
1	FH, CPB	5	291	33	5	21	Yes
2	Expired	NA	150	45	NA	NA	NA
3	BH	4	194	37	7	32	Yes
4	BH, CPB	4	367	50	3	21	Yes
5	BH	5	249	31	6	28	Yes

completed through four ports only. In two dogs the initial incision chosen for placement of the Endostab™ was not suitable and another port had to be created (total of 5 ports).

All four grafts that were completed were patent despite a target vessel diameter of less than 1 mm. Patency was confirmed with postoperative bench angiography (see Figure 6 ◎).

DISCUSSION

The aims of less invasive coronary artery bypass graft surgery are twofold: 1) to decrease the surgical trauma by minimizing access and 2) to obviate the need for CPB for its known negative effects [Diegeler 1998a, Diegeler 1998b]. The operation that ideally combines these goals for single bypass grafting of the LAD is the MIDCAB approach [Diegler 1997, Diegler 1998b]. Using computer controlled instruments, successful endoscopic bypass grafting of the LAD has been reported both for acute and chronic animal models [Stephenson 1998a, Stephenson 1998b, Ducko 1999], as well as in ongoing clinical trials [Boehm 1999, Carpentier 1999, Falk 1999a, Falk 1999d, Loulmet 1999, Mohr 1999a]. However, without an endoscopic stabilization device that would immobilize the heart under closed chest conditions, endoscopic bypass grafting on the beating heart was not possible [Falk 1999f]. Clinically, the Port-Access™ system for closed chest cardiopulmonary bypass and cardiac arrest was used. While this system enables endoscopic coronary artery bypass grafting (CABG), the use of CPB and retrograde perfusion adds a number of additional risk factors to a procedure that would otherwise be frequently performed without CPB [Mohr 1999b]. It was therefore our aim to develop an endoscopic stabilization device and to test it in a live animal model.

This study demonstrates the feasibility of endoscopic CABG on the beating heart. Using an endoscopic stabilization device, it was possible to locally immobilize the heart through a 12 mm trocar. Despite CO_2 insufflation there was no serious hemodynamic impairment. Although the study could not be completed in all of the dogs, it was demonstrated that it is possible to endoscopically perform an anastomosis on a vessel with a diameter of less than 1 mm on the beating heart using current computer enhanced technology. In three dogs the onset of VT necessitated resuscitation and CPB in order to finish the operation. These arrhythmias were not related to the use of the system nor to the stabilizer, but were most likely caused by ventilatory problems during the procedure.

Some limitations became evident during the study. The stabilization device in its current design is based on pressure immobilization only. We believe that a combined suction / pressure device (like the Octopus II®, Medtronic, Grand Rapids, MI) would offer additional stability. The lack of an articulating foot (the memory alloy pads open perpendicularly to the shaft but cannot be articulated in a second axis) makes determination of the best entry for the device difficult. In two animals, the stabilizer had to be repositioned and brought through a separate incision due to malplacement. Future devices should house a blower tip that also can be directed by the robotic system. A straight shaft should be avoided since it might interfere with the robotic instruments. A new prototype that addresses these issues is currently under development.

Once in place the Endostab™ provided sufficient stabilization despite its limitations. However, it could not provide a totally motionless working environment. Since the use of ten-fold optical magnification makes even small motions disturbing, further immobilization will probably be necessary. A promising alternative or adjunct is the Trans-Arrest™ method of pharmacologically induced overpaceable temporary cardiac arrest. It remains to be seen if total cardiac arrest even for a short period of time will

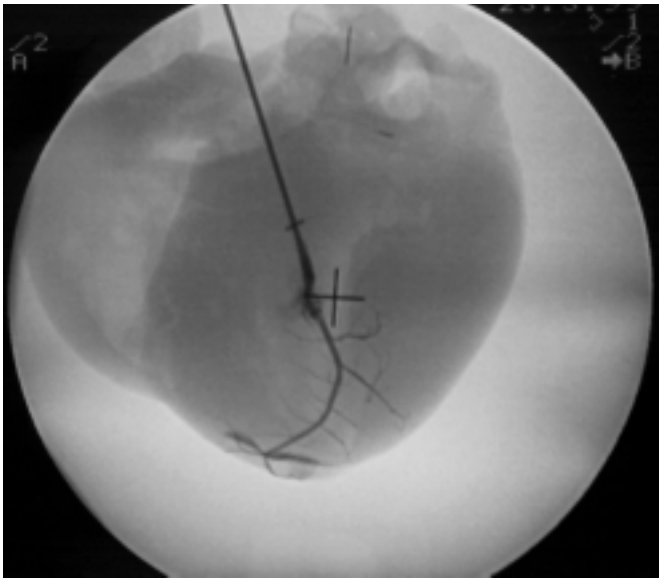

Figure 6. Ex-vivo bench angiography demonstrating a patent LITA graft to the second collateral branch that was performed endoscopically on the beating heart.

cause ventricular dilatation and thereby further decrease the already limited space between the heart and the chest wall.

Another problem that needs to be addressed is the application of vascular occlusion devices to temporarily stop blood flow in the target vessel. Ligation used in this animal model is not feasible in humans. The application of snares is difficult in an endoscopic environment, and the vessel occluders that are currently available are not well suited for use with the robotic instrumentation systems.

In conclusion, this study demonstrates the feasibility of endoscopic bypass grafting on the beating heart, and explores the need for adjunct technology in order to optimize the use of computer controlled instrumentation systems.

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REVIEW AND COMMENTARY

1. Editorial Board Member PB44 writes:

Where do you think this is heading?

What about ECG/laser controlled motion of all arms to eliminate the motion effect?

Authors' Response by Volkmar Falk, MD:

The evolution of computer enhanced surgery has just begun and it is very difficult to forsee what impact this new technology will have on our surgical practice. If endoscopic beating heart coronary artery bypass grafting can be performed with equal long term graft patency rates, it will be a true alternative to PTCA and stenting. Techniques for multivessel grafting have to be established. Using a right sided (access through the right chest) or transabdominal approach, it may be possible to graft both the right coronary artery as well as the LAD using both ITA's (which can be easily harvested through these approaches using the described telemanipulation system). For the circumflex or distal right coronary, exposure is once more the big hurdle, especially in an endoscopic environment.

Considering the possibilities of three-dimensional imaging techniques, it is conceivable that we will be able to simulate the procedure based on the individual anatomy of the patient. However, the techniques of registration and segmentation that are almost solved for more rigid structures (bones, brain) have to be developed for pliable and moving soft tissue (i.e., the heart). Registration is the determination of the spatial relationship of three

different coordinate frames: that of the patient, that of the 3D reconstruction data set (CT, MRI, angiogram) and that of the robot (a detailed description of the problems of registration is provided by Lea 1995). Segmentation describes the process of dividing a 3D-image (Voxels) according to discrete grey levels of the volume data into different homogenous regions. The goal of segmentation is the definition of a geometric model from volume data. If online registration becomes available, it might be possible to program parts of the surgical procedure based on the patient's model and have them performed automatically by the robot.

The concept of virtual immobilization to eliminate motion effects is also very appealing. By moving the camera and the instruments synchronous to the excursions of the beating heart, a motionless image (virtually arrested heart) can be created. However, the real time motion of the heart is very complex and varies due to a number of factors (filling pressures, frequency, rhythm, contractility, ventilation and the CO_2-insufflation pressure to name only a few). Virtual immobilization requires high computing capacity to compensate for this highly variable motion pattern. While the surgeon works on a motion-free image, the target in fact moves, so that the robot has to correct automatically for the spatial deviation. Considering the fact that working with 8-0 suture material on a 1mm vessel requires high precision, even minimally deviations would not be tolerated. In addition, in theory the telemanipulation system would then no longer work as an on-line system with the operator in steady control but rather be a true robot that is constantly programmed but essentially works on its own. This technique may imply some legal issues if used clinically.

Finally, despite all efforts, the human hand is currently still the most flexible tool available and will for some time challenge the engineers involved in these projects.

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2. Editorial Board Member SC389 writes:

How do the authors foresee this developing for future use by the majority of surgeons or will it be limited to a few?

Authors' Response by Volkmar Falk, MD:

It is difficult to make a forecast in terms of a general application of a new surgical technique. Right now there is very limited experience with the use of telemanipulation systems in cardiac surgery. When endoscopy was introduced clinically in other disciplines, some surgeons (usually termed early adopters) started to work endoscopically with great enthusiasm. The majority, however, had to be convinced by large databases that at some stage demonstrated the benefits of this approach. Today, it would be difficult to explain to a patient why he should have his gall bladder removed through a large incision while endoscopic cholecystectomy is the established standard therapy. In contrast, some other endoscopic techniques never found a broad application, because they were too complex to perform. What direction endoscopic coronary bypass grafting is going to take will not be obvious until a number of centers have presented their data. It will be a challenging task to demonstrate that this technique can compete with established approaches that yield excellent outcome at a reasonable cost. Although we have used the system in 80 patients by now, we are as yet unable to make a statement considering the future distribution and impact of such systems in the field of cardiac surgery. One has to keep in mind that other techniques that are currently developed (i.e., automatized anastomotic stapling or sewing devices, catheter techniques, new endoscopic instruments made for the use in CABG surgery) may change the way of robotic assistance as we see it now or may obviate the need for a robot at all.

3. Editorial Board Member MD125 writes:

This appears to me to be only a limited laboratory exercise related to commercial instrument development. The device is less than a first generation instrument, and is being simply experimented with. Work of this nature is early commercial work.

The authors cannot have it both ways. They cannot say that the two anastamoses were done on the beating heart when they were in fact done while fibrillating and/or on bypass. The purpose of the stabilizer is to avoid cardiopulmonary bypass. If "despite CO_2 insufflation there was little hemodynamic compromise", why did three of the five animals fibrillate? They fibrillated because of a combination of variables, none of which the authors can deny or control for, such as the stabilizer or system.

This "study" and its publication portray a "me first" phenomenon that is becoming too prevalent in the current environment. Two cases performed in this manner do not a make a successful series or serious validation of the technique. Many authors reviewing this manuscript will have collectively done dozens if not hundreds of original acts in the lab that help advance our courage and understanding, but which do not qualify as science. The authors need to work on their animal model to get survivors first, then work on a stabilizer that can be qualified as somewhat practical and useable, and do ten cases successfully. I qualify this as "work in progress, initial failures.

Authors' Response by Volkmar Falk, MD:

It is true that the value of the presented data is limited for the reasons mentioned above by the reviewer. Concerning the system, the version that was used in the lab is CE certified and is already being successfully used clinically in a number of centers. The device is not a first generation instrument but a very sophisticated tool that for the first time enables free motion in 3D-space in an endoscopic environment. Independent of a company name, the people who have created this system deserve our respect. Of course it is not the only system currently available and others will be developed soon.

It was not the intention of the manuscript to serve as a commercial presentation but to stimulate the discussion about a new surgical approach. Although this should not be worth mentioning, it is obviously important to emphasize that we are not selling this system and none of the authors has any financial relationship to the company that makes it.

Neither in the title nor in the text was the impression created that this work presents a "successful series" or "serious validation". I agree with the reviewer that this is work in progress and we are in fact progressing.

We were limited in the number of dogs solely because a number of authority restrictions make the dog model in Germany very difficult. We have switched to a swine model recently and continue our effort to develop an endoscopic beating heart coronary bypass technique. Of course swines fibrillate easily especially with temporary LAD occlusion and one lung ventilation.

In order to survive the animals throughout the operation, we regulary put the animals on CPB during these experiments. It is still a beating heart model although with some hemodynamic support. We all know that in patients with chronic CAD the tendency to fibrillate with temporary LAD occlusion is almost zero and that stabilization is well tolerated. In the experiments, it is important to solve the technical problems of the approach. Among those are: 1) how do we stabilize the heart through a throcar; 2) how can we provide temporary target vessel occlusion endoscopically; and 3) how do we deal with wall motion under high magnification. It was our intention to comunicate our early experience (including failures) and encourage other investigators that have undoubtfully performed 'hundreds of original acts' to do the same so that we can rapidly exchange ideas on these topics. We hope that endoscopic beating heart bypass grafting will soon become a reality no matter who is "first".