Blood Flow Pattern and Anastomotic Compliance for Interrupted versus Continuous Coronary Bypass Grafts

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ABSTRACT

Background: Use of the interrupted coronary anastomosis has largely been abandoned in favor of the more rapid continuous suturing technique. The Coalescent U-CLIP anastomotic device allows the surgeon to create an interrupted distal anastomosis in the same amount of time that it would take to create a continuous anastomosis. This acute bovine study examined the effect of the anastomotic technique on blood flow and vessel wall function.

Methods: End-to-side coronary anastomoses were created in an open chest bovine model using the left and right internal thoracic arteries and the left anterior descending coronary artery. All other variables except suturing technique were carefully controlled. In each animal, one anastomosis was completed using a continuous suturing technique and the other was performed in an interrupted fashion using the Coalescent U-CLIP anastomotic device. Volumetric flow curves through each graft were analyzed using key indicators of anastomotic quality, and anastomotic compliance was evaluated using intravascular ultrasound. Luminal castings were created of each vessel to examine the interior surface of each anastomosis for constrictions and deformities.

Results: The interrupted anastomoses created with the Coalescent U-CLIP anastomotic device showed significant differences with respect to anastomotic compliance, pulsatility index, peak flow, and percentage of diastolic flow. The cross-sectional area and degree of luminal deformity were also different for the two suturing techniques.

Conclusions: In this acute bovine model, interrupted coronary anastomoses demonstrated superior geometric consistency and greater physiologic compliance than did continuously sutured anastomoses. The interrupted anastomosis also caused fewer disturbances to the flow waveform, behaving similarly to a normal vessel wall. The combination of these effects may influence both acute and long-term patency of the coronary bypass grafts.

INTRODUCTION

The long-term patency of coronary artery bypass grafts is in part dependent on the quality of the anastomoses created during the procedure. Suturing technique has a direct effect on the quality of these anastomoses. The Coalescent U-CLIP anastomotic device allows facile creation of an interrupted anastomosis on essentially any vessel of 1-mm or greater caliber during both arrested and beating-heart procedures [Berdat 2002, Caskey 2002].

Suture technique can affect the internal configuration of an anastomosis. Interrupted suturing has been demonstrated to consistently produce the least deformity [Young 1978]. Clinically, long-term patency using interrupted technique has been documented through the results of studies conducted at the Cleveland Clinic [Loop 1979, Loop 1986]. The technique of choice when it comes to coronary artery bypass surgery is the continuous suturing method. This preference can be attributed to the relative ease of the technique as well as the considerable time-savings involved compared to an interrupted technique.

The Coalescent U-CLIP anastomotic device allows the surgeon to create an interrupted distal anastomosis in the same amount of time that it would take to create a continuous anastomosis [Hill 2001]. The interrupted anastomosis maintains the compliance of both the graft and native vessel. This compliance influences the pulsatile geometry of the anastomosis, therefore affecting the flow profile (volumetric flow versus time) through the graft and the anastomosis. In order to characterize and quantify the effect technique has on these fluid parameters, a study was conducted in which all other variables except suturing technique were controlled.

MATERIALS AND METHODS

Surgical Approach

Six male calves (45-65 kg) used for this acute study underwent surgery according to standard BioSurg operating procedures (Winters, CA, USA). Once calves were under general anesthesia (premedication: Telazol/glycopyrrolate; induction:

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ketamine/diazepam; maintenance: isoflurane), a catheter was placed in the right auricular artery, and the animal was placed in dorsal recumbence with the ventral thorax and caudal cervical regions prepped for surgery. A conventional midline sternotomy was used to expose the thoracic organs and vessels.

The left and right internal thoracic arteries (LITA, RITA) were harvested. Papavarine was applied topically to control vasospasm, and side branches were ligated with metallic hemoclips. Flow was evaluated for both vessels under free-flow conditions to establish a baseline of normal volumetric flow rate through the 2 arteries. These measurements were taken using either a Transonic HT312 single-channel flow meter (Transonic Systems, Ithaca, NY, USA) or a Butterfly flow meter (Medi-Stim, Oslo, Norway).

Heparin was administered (200 IU/kg) to provide systemic anticoagulation, and a conventional pericardiotomy and pericardial cradle was performed to position the left anterior descending coronary artery (LAD) for the anastomoses. A vascular snare (Retract-O-Tape) was placed around the LAD proximal to the intended anastomotic site, and pre-ischemic conditioning was used to prepare the heart for bypass. An Octopus3 Tissue Stabilization System from Medtronic Cardiac Surgery (Minneapolis, MN, USA) was used to stabilize the heart tissue around the LAD at the location of the intended anastomoses, and a Guidant CTS blower/mister (Cupertino, CA, USA) was used to clear blood from the field. The LITA and RITA were divided distally, trimmed equal to length, and beveled at equal lengths and angles at the ends (confirmed with calipers).

Two end-to-side anastomoses (LITA-LAD and RITA-LAD) 1 cm apart were created on the LAD using a randomly assigned suturing technique. Arteriotomy lengths were the same for both grafts within each animal. Size 7-0 Deklene II blue monofilament polypropylene suture (Genzyme Biosurgery, Cambridge, MA, USA) was used to create the continuous sutured anastomosis, and the Coalescent U-CLIP anastomotic device (S18-ST; Coalescent Surgical, Sunnyvale, CA, USA) was used for the interrupted anastomosis. The volumetric flow values in each conduit were found to be similar during free flow, allowing the randomization of only suture technique and not conduits. The LITA-LAD anastomoses were always proximal to the RITA-LAD anastomoses.

Flow Measurements

Following completion of the anastomoses, all snares were removed from the LAD and both conduits for a minimum of 5 minutes. The first set of volumetric flow rate measurements was then taken measuring flow through the LITA and RITA with everything open. The second set was then taken on each graft with the other one occluded using a bulldog clamp. The final set of measurements, plotting volumetric flow versus time, was obtained through each graft with the other graft and the LAD proximal to the anastomoses occluded so flow was through only the graft and anastomosis under evaluation. Each animal's electrocardiogram and blood pressure waveform were recorded simultaneously to the flow measurements.

Volumetric flow curves were analyzed using key indicators of anastomotic quality, including mean flow rate, peak flow rate, percent diastolic flow, and pulsatility index. Mean and peak flow rates were taken directly off of the flow tracing. Percent diastolic flow was calculated by computing the area under the flow curve for the time period of diastole (DF) divided by the total area under the curve (TF) for a complete cardiac cycle (100*DF/TF). The pulsatility index of each flow curve was calculated according to the following equation: pulsatility index = (maximum flow – minimum flow)/(mean flow). All values were calculated over a period of at least 5 cardiac cycles per flow curve.

Compliance Evaluation

Following volumetric flow measurements, the anastomotic compliance was evaluated using intravascular ultrasound (IVUS). To directly access the LAD for IVUS, a 4-mm vascular access graft was connected end-to-side to the distal LAD using either a continuous pattern of 7-0 polypropylene suture or Coalescent U-CLIP anastomotic device. The entire LAD and both anastomoses were then successfully imaged with IVUS using a 3.2 F Ultracross IVUS catheter. The IVUS catheter was placed in the LAD at the location of the widest opening for each anastomosis. Video IVUS footage for each of the described flow situations was captured onto super-VHS tapes for several cardiac cycles. These videos were transferred to digital media for computational image analysis. Anastomotic compliance was calculated by measuring the anastomosis opening at its largest opening width (W_{MAX}) and smallest opening width (W_{MIN}) over the cardiac cycle. The percent change in anastomotic opening [% Change = $100*(W_{MAX} - W_{MIN})/(W_{MIN})$] is proportional to the anastomotic compliance. Blood pressure and heart rate were similar for both measurements on each animal.

Postprocedure Methods

After completion of all outcome studies, the animal was killed. The heart, aorta, brachiocephalic trunk, and internal thoracic arteries were harvested *en bloc* for examination and perfusion fixation. The coronary ostia, brachiocephalic trunk, and internal thoracic arteries were perfused antegrade with 3 L of lactated Ringer's solution until all blood was cleared from the arteries. The heart, aorta, brachiocephalic trunk, and internal thoracic arteries were perfusion fixed with 10% neutral buffered formalin for approximately 30 minutes at a mean pressure of 100 mm Hg. A resin cast of the anastomoses and associated vessels was created by clamping the LAD proximally and distally and then injecting the vascular access graft (distal to both anastomoses) with StarVPS casting resin (Superior Impression Material, Vinyl Poly Siloxane; Danville Materials, San Ramon, CA, USA) at an approximate pressure of 100 mm Hg. Once the casting resin set completely, the tissue was removed to produce a cast (or model) representing the lumen of the native vessel, anastomoses, and arterial grafts. The castings were qualitatively analyzed by the surgeon and then sectioned transversely at each anastomosis for calculation of actual anastomosis cross-sectional area (in square millimeters) using computational imaging and measuring techniques. One casting, which was representative of the majority of the castings, was also sectioned vertically for comparison. Paired

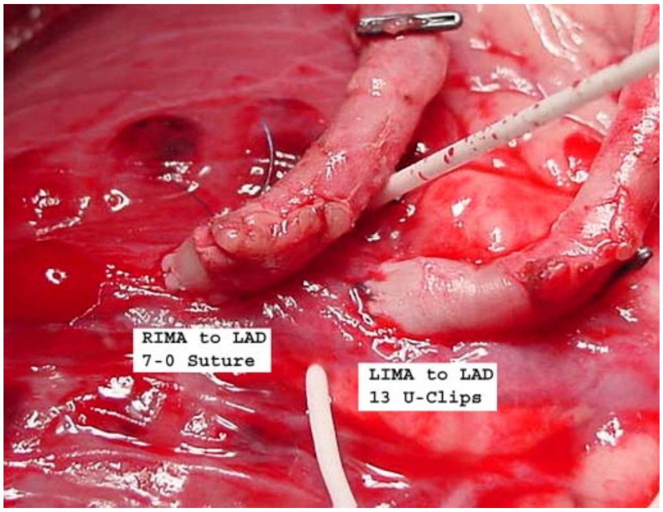

Figure 1. Side-by-side anastomoses. Right internal mammary artery (RIMA) to left anterior descending coronary artery (LAD) with continuous suture and left IMA (LIMA) to LAD with Coalescent U-CLIP anastomotic device.

t-test analysis was used to compare the means of each group for flow, compliance, and cross-sectional area.

RESULTS

The surgical procedure was well tolerated in the calf model. Figure 1 shows an intraoperative photograph of one pair of completed anastomoses with the anastomosis created with the Coalescent U-CLIP anastomotic device proximal to the continuous suture anastomosis. Significant differences were found in anastomotic compliance and cross-sectional area between the continuous suture group and the Coalescent U-CLIP anastomotic device group. Figure 2 shows examples of the IVUS images of two representative anastomoses. Each anastomosis, sutured and clipped, is shown, with measurements, at its respective minimum and maximum opening. Compared to the sutured anastomosis, the clipped anastomosis demonstrated 195% greater compliance (clipped = 31.3%; sutured = 10.6%; $P < .02$) (Table) in this study. This result is well visualized on the accompanying film clip. Figure 3 shows a picture of a luminal casting obtained from one of the animals postoperatively. The cross-sectional area of the clipped anastomosis (where the graft joins the LAD) was 57.6% larger than the sutured anastomosis (clipped = 8.40 mm^2; sutured = 5.33 mm^2; $P < .02$) (Table). Figure 4 shows vertically and horizontally sectioned castings of both the sutured and clipped anastomoses, demonstrating this difference.

With regard to flow measurements, mean volumetric flow rates through the grafts for the sutured and clipped anastomoses were 56.94 mL/min and 61.12 mL/min, respectively, and did not differ significantly ($P = .27$), indicating similar outflow resistance. In terms of peak flow, however, the mean peak flow of the clipped anastomoses was 34.7% lower than that of the sutured anastomoses (clipped = 222.28 mL/min; sutured = 340.62 mL/min; $P < .01$) (Table). This difference achieved significance. Compared to the continuously sutured anastomoses, the mean pulsatility index for the clipped anastomoses was 39.9% lower (clipped = 4.66; sutured = 7.75; $P < .02$; Table 1), indicating a smaller likelihood of regional anastomotic abnormality. Calculated values of the percent diastolic flow for clipped anastomoses were 42.5% greater than for sutured anastomoses (clipped = 57%; sutured = 40%; $P < .05$) (Table). This difference also achieved significance.

DISCUSSION

By virtue of its compact size and elimination of knot tying, the Coalescent U-CLIP anastomotic device facilitates performance of a distal coronary anastomosis when space is a commodity. This device is useful for coronary bypass surgery on the beating heart and promising with regard to future applications in endoscopic and robotic surgeries. It also provides rapid creation of an interrupted anastomosis, which may enhance anastomotic quality in any setting. Use of the interrupted coronary anastomosis had largely been abandoned in favor of the more rapid running polypropylene technique. Reintroduction of the interrupted anastomosis with the addition of economy of time and space prompted us to investigate the effect the two different techniques have on anastomotic performance.

Studies looking at anastomotic configuration have found that the most consistent and least deformed configuration occurred when interrupted technique was employed [Young

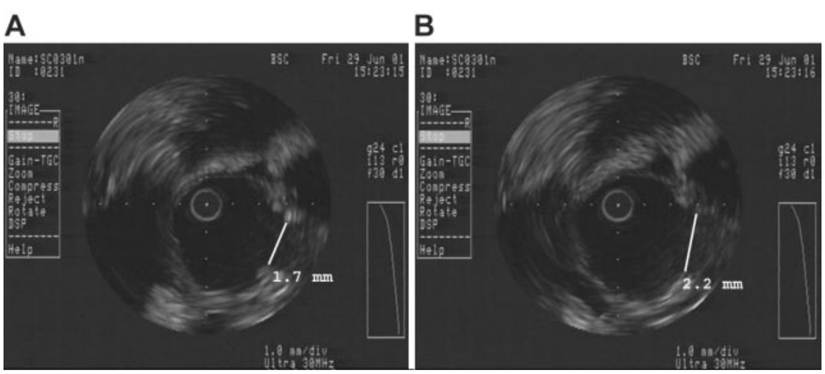

Figure 2. Intravascular ultrasound images of sutured anastomosis at (A) minimum opening width and (B) maximum opening width.

Results of Transit Time Flow Measurement Analysis, Intravascular Ultrasound, and Luminal Casting

	n	Continuous	U-CLIP	*P*
Flow measurements				
Mean flow, mL/sec	6	56.94 ± 16.72	61.12 ± 5.37	.260
Peak flow, mL/sec	6	340.62 ± 143.77	222.28 ± 109.89	.004
Diastolic flow, %	6	40.04 ± 20.23	57.04 ± 15.87	.049
Pulsatility index	6	7.75 ± 4.24	4.66 ± 2.53	.014
Intravascular ultrasound analysis				
Compliance, %	6	10.62 ± 9.73	31.33 ± 17.91	.012
Luminal castings				
Anastomotic cross-sectional area, mm^2	5	5.33 ± 1.85	8.40 ± 1.88	.011

1978; Shioi 1984]. Furthermore, it was noted that the external appearance of the anastomosis did not reliably reflect the internal configuration [Young 1978]. The thermoplastic luminal castings from this study confirm that the 3-dimensional symmetry of the vessels and the anastomotic surface area was greater using the interrupted technique. All of the anastomoses in our study were created by cardiac surgeons who have sewn thousands of human coronary artery bypasses using running polypropylene suture. Nevertheless, the interrupted anastomosis was consistently more uniform. In addition, the castings demonstrated the presence of a ridge of tissue around the internal margin of the running anastomoses, which was absent in the anastomoses created with the Coalescent U-CLIP anastomotic device. This finding becomes even more obvious when cross-sections of the castings are cut for measurement as seen in Figure 5.

In addition to the geometric consequences of the interrupted technique, there is evidence that it might also affect the physiologic performance of the anastomoses because of anastomotic compliance [Klein 1982; Tozzi 2001]. This feature was demonstrated in the systemic circulation by Tozzi et al, who created internal mammary artery–to–carotid artery anastomoses in a swine model [Tozzi 2001]. Piezo-electric crystals were used to measure the caliber of the anastomoses throughout the cardiac cycle. Tozzi et al found that the biomechanical properties of the vessels were best preserved with the interrupted anastomoses, which provided a substantially higher cross-sectional anastomotic compliance. IVUS measurements from this study demonstrate significantly more compliance in the interrupted mammary artery–to–coronary artery anastomoses. The diameter of the interrupted anastomosis varied by 30% during the cardiac cycle, whereas that of the running anastomosis changed by 10%. Although both the interrupted and the running-suture anastomosis are patent, the interrupted anastomosis does provide more physiologic variation in the anastomosis caliber, preserving vessel wall dynamics and resulting in a more physiologic flow pattern with significantly lower peak flows and a greater diastolic component.

Coronary blood flow to the left heart is predominantly diastolic, with only one third occurring in systole. The running suture anastomosis produced a significant increase in the systolic component and therefore peak flow velocity, as reflected in the pulsatility index derived from the transit time flow measurements. The formula for the pulsatility index is: maximum flow – minimum flow/mean flow. Either a rise in the maximum flow or a negative value for the minimum flow will raise the pulsatility index. Minimum flow can become negative if there is competitive flow from the proximal target vessel. This situation was eliminated in our study by total occlusion of the target vessel proximal to the anastomosis during measurements. The pulsatility index is useful clinically as an indicator of anastomotic stenosis and a criterion for revision in the operating room [Walpoth 1998, VanHimbergen 1999, D'Ancona 2000]. This index is based on values collected from many human bypass grafts. The pulsatility index in the bovine model appears to have a higher baseline than in humans. This difference may be related to ventricular mass and wall tension in the relatively thick bovine heart. There

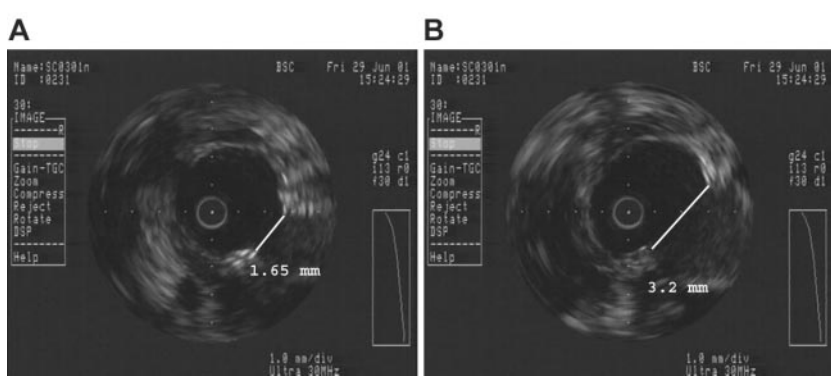

Figure 3. Intravascular ultrasound images of clipped anastomosis at (A) minimum opening width and (B) maximum opening width.

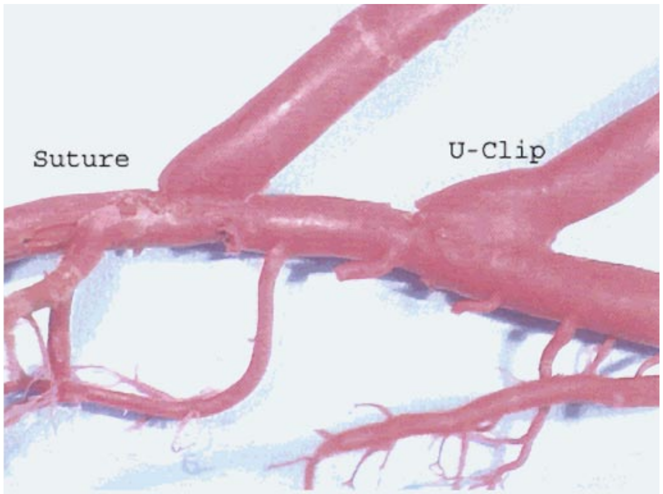

Figure 4. Photograph of luminal casting of side-by-side anastomoses.

are no large studies of bovine flow indices to set baseline parameters. In our study, the sewn and the interrupted anastomoses are all patent and performing under the same conditions of hemodynamics and runoff. The only difference is the anastomotic technique. Technique difference provides enough alteration in vessel mechanics, and thereby flow waveform, to result in a significantly lower pulsatility index for the interrupted anastomosis. Notably, mean flow was not significantly different for the two groups. The resistance of the distal bed largely determines mean flow reference, and the lack of any difference in the values confirms that both groups were subject to the same outflow resistance.

The geometric and physiologic qualities of the anastomosis may have both short and long-term implications in the coronary circulation. Acutely, the likelihood of achieving the largest possible cross-sectional area is enhanced by diminishing the potential for irregularities in anastomotic configuration by using an interrupted technique. Furthermore, physiologic compliance appears to translate into more physiologic flow. Abnormal flow patterns and wall shear stress at the anastomosis likely contribute to intimal hyperplasia, leading to anastomotic stenosis over the long term. Less flow disturbance at the anastomosis may lead to less intimal injury and subsequent hyperplasia [Morinaga 1985, Sottiurai 1989, Ballyk 1998]. This hypothesis supported by histopathologic evidence that intimal hyperplasia of the internal mammary–to-coronary anastomosis occurs first at the internal ridge of the running anastomosis—a feature seen on castings of the running anastomosis, but not the interrupted anastomosis. A second focus is created in the hood of the graft. This second area of intimal injury occurs later and may be the result of changes in local hemodynamics caused by the stenosis being created at the first site of injury [Ojha 2000]. When bovine anastomoses created with the interrupted technique using the Coalescent U-CLIP anastomotic device were evaluated for evidence of inflammation and hyperplasia out to 6 months, the changes were minimal and localized to the 8 or 10 points where the nitinol clips attached the vessels [Hill 2001].

In 1986, Dr. Floyd Loop et al published a landmark study demonstrating a 96% 10-year patency rate for internal mammary artery grafts to the anterior descending coronary artery [Loop 1986]. The distal anastomoses in the Loop et al study were created with an interrupted technique. More recently, Caskey et al performed 6-month angiographic follow-up on 18 LIMA-to-LAD grafts using the Coalescent anastomotic device. All were Fitzgibbon grade A with an average anastomotic stenosis of –4.2% [Caskey 2002].

In this acute bovine model, the interrupted coronary anastomosis demonstrated superior geometric consistency and greater physiologic compliance. The interrupted anastomosis caused fewer disturbances to the flow waveform, behaving more like a normal vessel wall. This combination of geometric and physiologic effects may influence both acute and long-term patency. Evidence that the interrupted technique provides a superior anastomosis, along with the ease of application of this device, may provide impetus for a return to interrupted technique in coronary artery surgery.

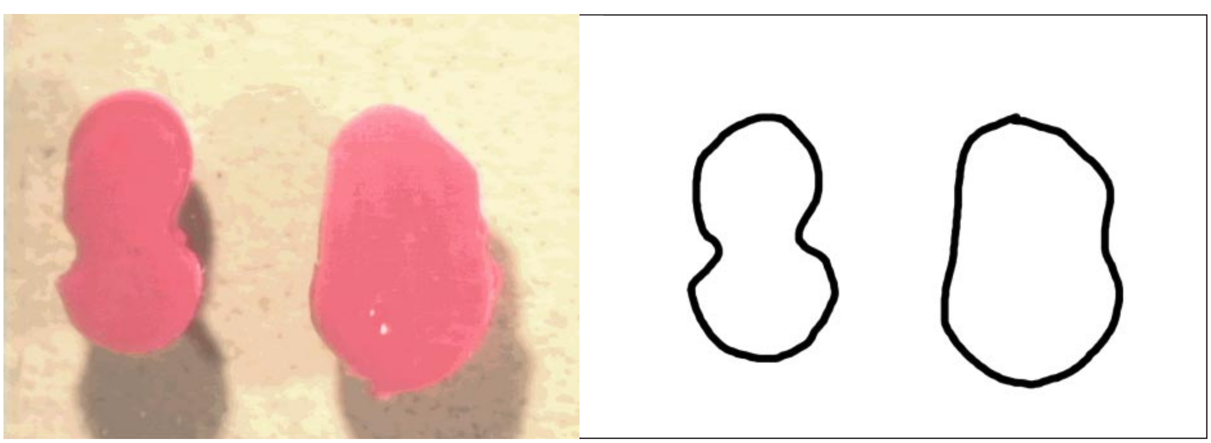

Figure 5. Cross-sections of anastomosis castings.

DISCLOSURE

This study was sponsored by a grant from Coalescent Surgical, Inc, Sunnyvale, CA, USA.

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REVIEW AND COMMENTARY

1. Editorial Board Member YE186 writes:

a) Although both of Loop's papers reported 96% patency, only 35% and less of patients had catheter proof of patency. This result is unacceptably low to say much about patency in the entire series per se. The improved survival in the internal mammary artery group was a statistical finding, not a patency finding.
b) Also, Fitzgibbon had catheter patency on more than 90%, so comparison is not appropriate. There are more than 10 papers in the literature that document more than 97% patency early, with a running suture, and this is an acute study.
c) I would also suggest that most surgeons do not agree that "special precautions" need be taken with running sutures, referencing a 24-year-old report. It is pure speculation that Fitzgibbon's lower patency rate was due to the type of construction, especially given the low catheterization rate reported in both Loop papers. Maybe all those whose anastomoses failed died.

Author's Response by Marc Gerdisch, MD:

The introduction and end of the discussion describe the reason why the study was undertaken, as well as why there may be continued interest clinically in interrupted technique. Interrupted technique used to be cumbersome and it no longer is. Recent studies [Tozzi 2001] have demonstrated the compliance in the interrupted anastomosis in the systemic circulation. We undertook to quantify that compliance in the coronary circulation and also characterize the impact on coronary blood flow.

a) As pointed out in the discussion, intimal hyperplasia and anastomotic stenosis are thought to be related to local hemodynamics. These hemodynamics are of course dictated by the geometry and physiologic performance of the anastomosis. Our study results demonstrate that both of these parameters are different for the interrupted versus the running anastomosis. The interrupted anastomosis clearly has greater capacity to perform as an integral part of the vasculature and not impart abnormalities to the flow waveform. Minimization of changes in the local hemodynamics could have positive implications for long-term anastomotic patency. We thought it worthwhile to mention Dr. Loop's findings and the fact that these anastomoses were created with an interrupted technique. Although the study is based on incomplete follow-up, it remains one of the most powerful statements regarding the longevity of coronary bypass grafts and the most frequently quoted reference in the literature on mammary graft patency.

b) The Fitzgibbon paper was referenced in the original manuscript simply because it is the only other very large study with long-term patency results. Attention was called to the suture technique, raising the possibility that it might have played a role. The Fitzgibbon reference has since been removed, as the intention was not to make direct comparison to Dr. Loop's studies. With regard to early patency, although these studies involve small groups of patients, the results of the Caskey et al study [2002] and those presented by Dr. Wolf at the 2002 meeting of the American Association for Thoracic Surgery [Wolf 2002] reveal not only superb patency but also, remarkably, fewer anastomotic stenoses than comparable studies using running suture techniques.

c) A 24-year-old study was referenced because our findings were similar. The age of the study really has no relevance. Running-suture technique was performed the same way then as it is now. Dr. Mack refers to any anastomosis with less than 50% stenosis as perfect [Mack 1999], and the POEM study revealed an average 24% stenosis for both on and off-pump LIMA-to-LAD grafts [Caskey 2002]. Using the Coalescent anastomotic device to create interrupted anastomosis off-pump, Dr. Caskey's data and the multicenter data reported by Dr. Wolf indicated –4.2% and –2.3% stenosis, respectively.