

Clinical and six-month angiographic evaluation of coronary arterial graft interrupted anastomoses by use of a self-closing clip device: A multicenter prospective clinical trial

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Objectives: To evaluate the safety and effectiveness of a self-closing surgical clip with an interrupted technique in left internal thoracic artery to left anterior descending artery bypass grafting.

Methods: Eighty-two patients were enrolled and treated (February 2000 through August 2001) in a prospective, nonrandomized, multicenter trial. Left internal thoracic artery to left anterior descending artery anastomoses were performed in 60 off-pump coronary artery bypasses (73%), 12 conventional coronary artery bypass grafting (15%), and 10 minimally invasive direct coronary artery bypass (12%) procedures. Angiograms (64 to 383 days, mean 200 days) were obtained on 63 patients (77%). Qualitative and quantitative angiographic assessment was performed by an independent core laboratory.

Results: The self-closing surgical clip was used for 82 left internal thoracic artery to left anterior descending artery interrupted anastomoses without the requirement for knot tying or primary suture management. Minimum left internal thoracic artery to left anterior descending artery anastomosis time was 3 minutes. There was one perioperative and one late death (both not heart related) and one reexploration for bleeding unrelated to the anastomotic site. FitzGibbon grades were as follows: A (n = 60, 95.2%), B (n = 3, 4.8%) including one kinked left internal thoracic artery, and O (n = 0, 0%). Quantitative analysis (n = 57) showed mean lumen diameters of left internal thoracic artery proximal to the anastomosis of 2.1 mm, at anastomosis of 2.0 mm, and in the left anterior descending artery distal to the anastomosis of 1.9 mm. The average ratio of the anastomosis to the left anterior descending artery diameter was 1.14 (0.45 to 1.93). Anastomotic stenosis as a percentage of average left internal thoracic artery to left anterior descending artery diameter was -2.3%, comparing favorably with results (23% to 24%) reported from the Patency, Outcomes, Economics, Minimally invasive direct coronary artery (POEM) bypass study.

Conclusions: The interrupted technique, facilitated by a self-closing anastomotic clip, yields favorable 6-month angiographic results when compared with other published studies.

The frequent presumption of a long-term (> 10 years) left internal thoracic artery (LITA) to left anterior descending artery (LAD) patency rate of 96% by many heart surgeons has recently been called into question. Results of 96% patency rates at 5 and 10 years, reported by Lytle,¹ Loop,² and their associates at the Cleveland Clinic in 1985 and 1986, were obtained by use of a compliant, interrupted suture technique in conjunction with cardiopulmonary bypass. Extrapolation of these benchmark Cleveland Clinic results to the continuous suture

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**Published References to "Patency"
or "Quality" and "CABG"**

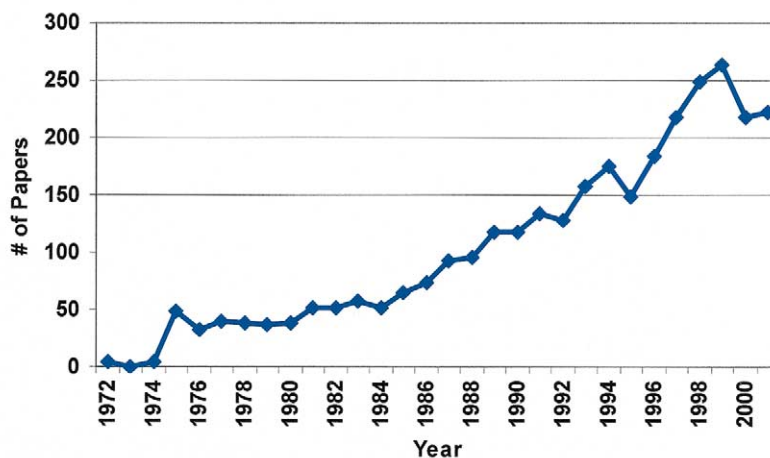


Figure 1. The number of studies that come up each year from the MEDLINE search “(patency or quality) and CABG.”

technique and to current minimally invasive procedures including off-pump or beating heart surgery is not supported by other published studies³⁻⁵ (Table 1). These studies have invariably used the more expedient continuous suture technique.^{3,4} Reintervention rates for coronary artery bypasses have recently been reported to be as high as 39% within 8 years.⁶

The emergence of beating heart surgery has resulted in a widespread reassessment of anastomotic quality. This is illustrated by the significant upswing in the number of articles about coronary artery bypass grafting (CABG) published with reference to “patency” or “quality” (Figure 1) since the introduction of the off-pump technique. It is clear that the *raison d’être* of heart surgery must be a high-quality anastomosis, and the fact that this must frequently be achieved on a beating heart while working through smaller incisions continues to motivate the development of improved surgical techniques and facilitating surgical technology.

One of the issues that recently has emerged again in this context is the question of continuous versus interrupted suture technique. The vascular anastomosis originally developed by Alexis Carrel, 1912 Nobel Laureate in Medicine, used a modified interrupted technique. This interrupted suture technique was initially adopted by heart surgeons as surgical revascularization became the standard of care in the late 1970s. Results published in now-seminal articles by Loop¹ and Lytle² and associates have been based on this interrupted approach. Subsequently, as CABG procedures became more prevalent, there occurred a shift in basic anastomotic methods away from the established interrupted

TABLE 1. 100+ patient ITA patency studies with ≥ 5-year angiographic follow-up

Author	Publication date	Time (years)	Reported patency
Loop	1986	10	96%
Lytle	1985	≥5	96%
Tyras	1980	5	90%
Ivert	1988	5	89%
Ivert	1988	10	87%
Okies	1984	5	81%
Fitzgibbon	1996	≥5	80%

technique to a more expedient, continuous suture approach in response to pressures associated with resource use and operating time. Microvascular, pediatric and neurovascular surgeons have demonstrated that there are significant advantages to using an interrupted technique.^{7,8} However, until recently, issues of suture management, manpower, and resource use continued to inhibit adoption of this interrupted technique.

This study was intended to formally revisit the use of the interrupted technique to improve anastomotic patency and quality by use of a now well-established self-closing clip technology. The Investigational Device Exemption– (IDE) based clinical trial was designed in consultation with the Food and Drug Administration (FDA) with the objective of demonstrating the safety and effectiveness of the Coalescent Surgical U-Clip anastomotic device (Sunnyvale, Calif) for specific cardiovascular/CABG indications.



Figure 2. Photograph of the study device (Coalescent U-Clip device).

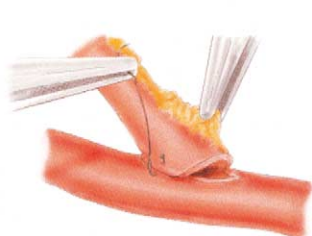


Fig 3a.

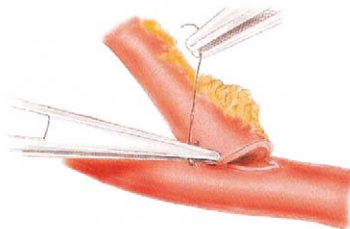


Fig 3b.

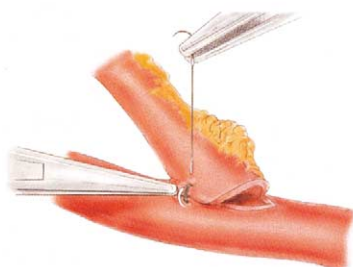


Fig. 3c.

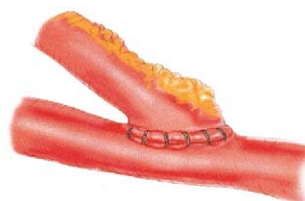


Fig 3d

Figure 3. a, Placement of U-Clip device; b, pressure applied to release; c, U-Clip closure and removal of needle and flexible member; d, finished anastomosis.

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Figure 4. Completed LITA-LAD anastomosis with "cobra-head" appearance.

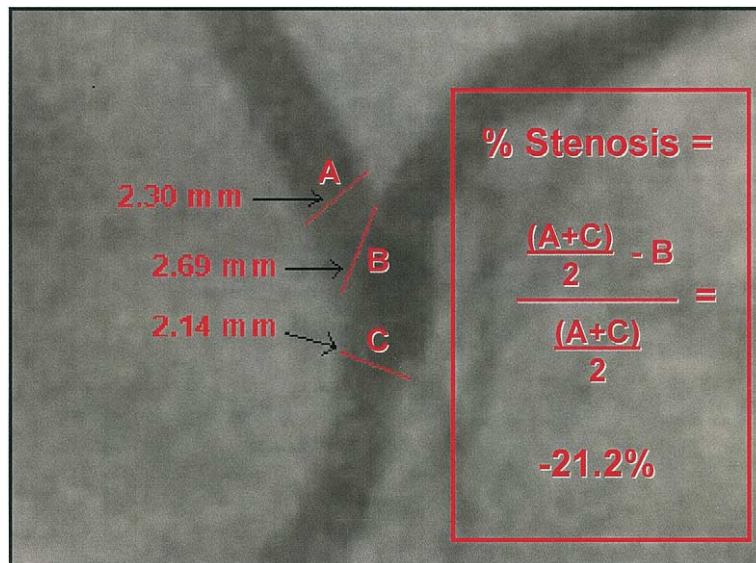


Figure 5. Anastomotic dimensions determined during QCA. A, portion of LITA graft immediately proximal to anastomosis; B, anastomosis dimension (typically defined as MLD); C, native LAD immediately distal to anastomosis site. Calculation for average percent diameter stenosis is shown.

Materials and Methods

This was a prospective, nonrandomized study designed to compare interrupted anastomotic technique facilitated by the U-Clip study device with historically published results obtained by use of continuous suture. The requirement for approximately 60, 6-month postoperative angiograms was established by use of an FDA-suggested method. Enrollment continued until it was clear that the minimum number of required 6-month angiograms would be obtained.

The U-Clip (Figure 2) comprises four basic components: a self-closing clip, a release mechanism, a flexible member, and a needle. Surgical application consists of (1) piercing the desired tissue with the needle and placement of the clip by pulling the flexible member and release mechanism through the tissue (Figure 3, a), and (2) closure of the clip and release of the delivery mechanism by the application of pressure (Figure 3, b). Once released, the needle and flexible member are removed and dis-

TABLE 2. Enrollment, demographics, and follow-up

Site	Treated	Sex		Average		Patient follow-up	
		M	F	Age	BMI	No	Angiography
DSH	31	26	5	65.4	29.2	31	19 (61%)
OSU	18	13	5	65.6	27.6	18	16 (89%)
SJH	18	18	0	64.4	29.3	18	17 (94%)
WASH	7	6	1	63.9	27.4	7	7 (100%)
UNMC	7	6	1	67.1	30.8	7	3 (43%)
KFH	1	1	0	65.0	29.1	1	1 (100%)
Total	82	70	12	65.2*	28.8†	82	63 (77%)

DSH, Desert Samaritan Hospital; OSU, Ohio State University; SJH, St Joseph’s Hospital; WASH, Washington Hospital Center; UNMC, University of Nebraska Medical Center; KFH, King Fahad Hospital.

*P = .95.

†P = .38.

TABLE 3. Procedural summary (core lab measurements)

Site	No. beating heart	No. median sternotomy	Average diameter (mm)		
			LITA	Anastomosis	LAD
DSH	31/31	28/31	2.11	1.78	1.88
OSU	13/18	13/18	2.00	2.09	1.68
SJH	18/18	17/18	2.32	2.25	1.99
WASH	7/7	7/7	2.17	1.84	1.91
UNMC	1/7	6/7	1.80	1.93	2.13
KFH	0/1	1/1	1.40	1.32	0.96
Total	70/82	72/82	2.12*	2.00†	1.86‡

*P = .3.

†P = .07.

‡P = .22.

carded (Figure 3, c). Anastomoses are formed in the usual manner with a number of clips applied in a circular fashion around the anastomotic site (Figure 3, d). Individual placement of U-Clips results in a desired “cobra-head” appearance of the completed anastomosis (Figure 4).

Study inclusion and exclusion criteria were adopted from the joint American College of Cardiology and American Heart Association practice guidelines for coronary artery bypass graft surgery⁹ and coronary artery angiography.¹⁰ Other inclusion criteria were ages between 18 and 80 years, body mass index (BMI) of less than 35 kg/m², and left ventricular ejection fraction of 30% or greater. The exclusion criteria of this study are listed in the Appendix.

A total of six clinical sites and eight principal investigators participated in the study. Investigators were allowed to use either arrested heart or beating heart techniques, depending on their individual preference and the operative situation. Each investigator was given the opportunity to use the study device to complete anastomoses on a porcine heart ex vivo before the device was used clinically. This was the only training that each investigator received before beginning the study. Patients meeting all inclusion criteria and signing informed consent were enrolled into the study. The study device was used to complete a LITA-LAD interrupted anastomosis in the same basic manner as suture, with the exception of knot tying. Case report forms were completed per protocol. Patients were treated after operation in the usual and customary

TABLE 4. Core lab results

Site	TIMI flow			Patency %	Fitzgibbon grade			Average ratio anastomosis/LAD	Average % stenosis at anastomosis
	3	2	1		A*	B†	0‡		
DSH	17	0	2	100	17	2	0	1.05	6.4%
OSU	15	0	1	100	16	0	0	1.28	-12.8%
SJH	17	0	0	100	17	0	0	1.17	-4.2%
WASH	6	1	0	100	7	0	0	1.00	4.9%
UNMC	3	0	0	100	2	1	0	0.91	5.0%
KFH	1	0	0	100	1	0	0	1.38	-11.9%
Total	59	1	3	100	60	3	0	1.14	-2.3%§

*<50% stenosis graft trunk or anastomosis.

†>50% stenosis.

‡Occluded.

§P < .1.

fashion, with no additional anticoagulation administered. All patients were followed up at approximately 2 weeks and then again at 6 months after discharge.

The core angiographic laboratory at Stanford University Medical Center, under the direction of Edwin Alderman, was used to independently evaluate all LITA-LAD anastomoses. Alderman (using standard angiographic computer software) personally completed the quantitative analysis of all of the postoperative angiograms obtained during this study. Standard measurements taken are shown in Figure 5 along with the calculation described below.

Results

Enrollment, Demographics, and Follow-up

Seventy men and 12 women with a mean age of 65.2 years (43 to 81) and a mean BMI of 28.8 kg/m² (19.7 to 40.6 kg/m²) were enrolled and treated (Table 2). All patients had follow-up office visits, and a total of 63 (77%) consented to return for detailed angiographic study at an average of 200 days after operation (64 to 383 days). Two angiograms (3%) were completed before 160 days (64 and 110 days), 47 (74%) were completed between 160 and 200 days after operation, 11 (17%) were completed between 200 and 300

days, and 4 (6%) were completed at more than 300 days after operation.

Intraoperative Summary

LITA-to-LAD interrupted anastomoses were completed by use of the U-Clip in 82 total procedures; 70 (85%) were completed off-pump on the beating heart (Table 3). A total of 72 (88%) were completed by median sternotomy approach including 60 (73%) off-pump coronary artery bypass (OPCAB) procedures and 12 (15%) classic CABG (median sternotomy, on pump) procedures. The remaining 10 (12%) were completed by use of a minimally invasive direct coronary artery bypass (beating heart) (MIDCAB) or video-assisted direct coronary artery bypass procedure.

The average LITA diameter (immediately proximal to the anastomosis) and LAD (immediately distal to the anastomosis) lumen diameters (measured quantitatively at time of follow-up angiography) were 2.1 and 1.9 mm, respectively (Table 3), with 30% of LADs less than 1.5 mm. Two cases were excluded during operation per the protocol exclusion requirement of “unexpected intraoperative findings creating an unreasonable intraoperative risk, an increased probability of postoperative complications in terms of recovery or later completion of postoperative angiogram.” As reported earlier,¹¹ one of these two patients undergoing an OPCAB procedure required an unusually long onlay patch-like anastomosis because of a severely calcified target vessel. The second patient (the first case attempted at one of the institutions) was excluded during operation because of what the surgeon reported as a “LAD and LITA wall thickness mismatch.”

The average number of U-Clips used was 11.8 with a minimum of six and a maximum of 24. Mean LITA-LAD anastomosis time was 12.4 minutes (3 to 35 minutes) overall and averaged less than 10 minutes after the first 8 cases. These post initial learning curve times are entirely consistent with typical times required for completing anastomoses on beating hearts by use of a continuous suture technique. Each investigator reported the occasional requirement for the removal of one or more clips and subsequent replacement without problem or difficulty. There was one perioperative death (duodenal perforation) and one late death (respiratory failure at 11 days after operation). One reexploration was performed for bleeding found to be unrelated to any of the anastomotic sites. One perioperative myocardial infarction occurred in 1 patient. This adverse event was reported to be unrelated to the LAD target distribution. No adverse events, either during operation, before discharge, or at follow-up, were attributed to the U-Clip. There were 2 cases of arrhythmia, 1 transient ischemic attack, and 1 case of pleural effusion reported during the 6-month follow-up period. Including all treated patients, the reported 6-month major adverse cardiac events (MACE) rate was 2.4% (2/82),

TABLE 5. Analysis of FitzGibbon grade B results

Patient	FitzGibbon grade	Ratio	%	TIMI score
		anastomosis/LAD	Stenosis at anastomosis	
UNMC1 (Patient 1 of 7)	B	0.45	40.9%	3
DSH1 (Patient 1 of 31)	B	0.83	26.1%	3
DSH12 (Patient 9 of 31)	B	0.48*	45.9%*	1

*Estimated. Competing native vessel flow impaired anastomotic measurement.

both unrelated to the use of the study device. There were no differences in morbidity or mortality rates or obvious clinical outcome among the 63 patients who returned for follow-up angiography and the 19 patients who refused.

Core Laboratory Analysis

The core angiographic laboratory at Stanford used both qualitative and quantitative methods to evaluate each anastomosis. Qualitative methods included estimates of Thrombosis In Myocardial Infarction (TIMI) trial flow and general assessments of patency. More definitive, quantitative techniques included assignment of FitzGibbon score that included not only the quality of the anastomosis (greater or less than 50% stenosed) but graft quality and patency as well. Finally, the most quantitative analysis was completed by measuring the luminal diameters of the LITA distal and immediately proximal to the anastomosis, the anastomosis itself, and the luminal diameter of the native LAD immediately distal to the anastomosis. These dimensions made it possible to calculate the ratio of the anastomosis to the LAD and also the average percent diameter stenosis, as used in the Patency Outcomes Economics MIDCAB (POEM) study (see discussion below).

Angiograms were completed on a total of 63 out of 82 treated patients (76.8%). All 63 (100%) LITA-LAD anastomoses completed with the U-Clip device were found to be patent at follow-up (Table 4). The core angiographic laboratory graded 60 (95%) of the 63, 6-month postoperative angiograms as FitzGibbon grade A (< 50% stenosis of either graft trunk or anastomosis when compared with LAD) and three (5%) as FitzGibbon grade B (> 50% stenosis), including one kinked LITA graft unrelated to the anastomosis. There were no occlusions (FitzGibbon grade O) observed. Detailed quantitative analysis (n = 57) showed mean lumen diameters of the LITA proximal to the anastomosis of 2.1 mm, at the anastomosis of 2.0 mm, and in the LAD distal to the anastomosis of 1.9 mm (Table 3). The average ratio of the anastomosis to the LAD diameter was 1.14 (0.45 to 1.93). Anastomotic stenosis as a percentage of average LITA/LAD diameter was -2.3%, excluding the one FitzGibbon grade B result that could not be quantified because of competing native vessel flow and including

LIMA/LAD Study Patency Comparison with Angiographic Follow-Up at 6 Months

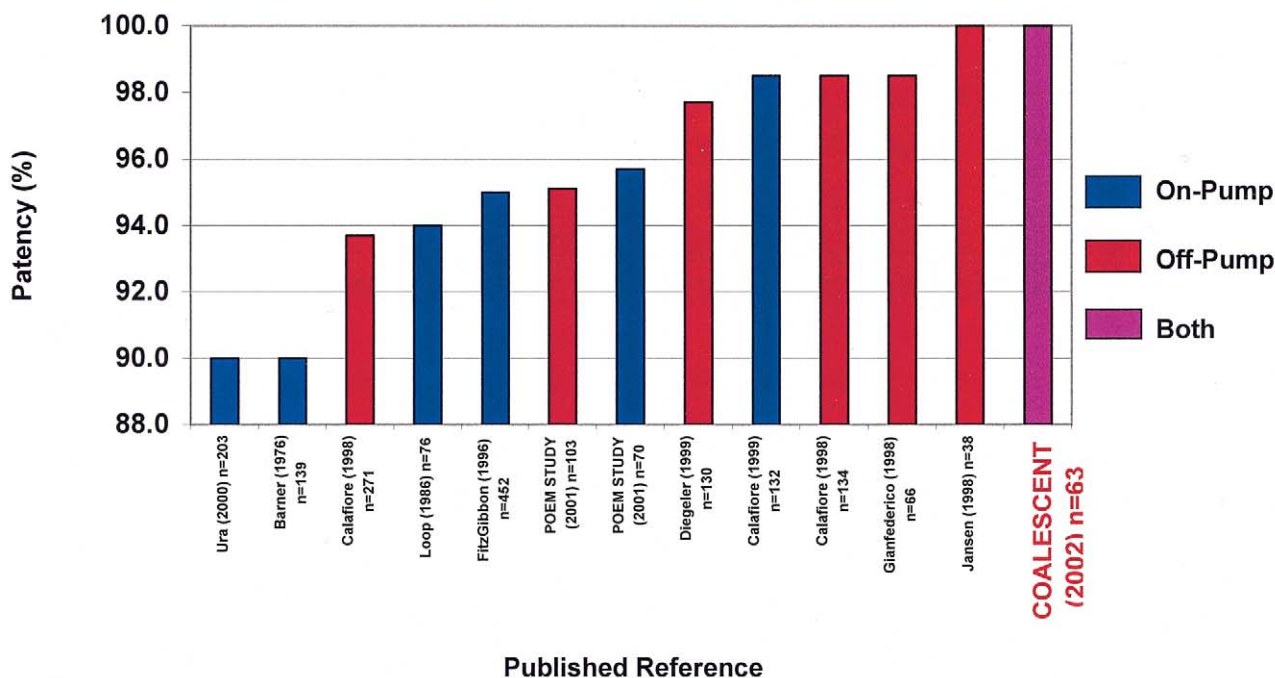


Figure 6. Patency comparison among studies with angiographic analysis at 6 months.

30 instances (48%) where the anastomosis was found to be larger than the reference vessel diameter.* Fifty-nine cases (93.7%) were graded TIMI grade 3, one (1.6%) was graded TIMI grade 2, and three (4.7%) were graded TIMI grade 1 because of poor distal bed runoff (Table 4). There was very poor correlation between these subjective TIMI flow measurements and objective quantitative analysis (Table 5). Again, this highlights the importance of quantitative angiographic analysis (QCA) for evaluating new techniques and technologies in CABG procedures.

Further analysis of the three instances of FitzGibbon grade B results (Table 5) revealed that 2 of these 3 cases represented the first cases completed by each of two surgeons. In two instances the ratio of the anastomosis to LAD was just under 50% (0.45 and 0.48). In the third case the ratio was greater than 50% (0.83); however, a kink in the LITA was measured at less than half of the LAD luminal diameter and, consequently, the result was categorized as grade B. There was no correlation with TIMI flow because two of the three grade B results showed perfect TIMI grade 3 flow.

*This percent diameter calculation was made using the identical methodology—including treatment of negative percent diameter stenosis results—used by the Cardiovascular Research Foundation (CRF) for the POEM study.

Discussion

The results from this clinical study can be compared with three different categories of published studies: (1) studies (both on and off pump) reporting simple qualitative patency only (with or without TIMI flow) between 6 and 12 months after operation (Figure 6); (2) studies reporting more quantitative FitzGibbon scores between 6 and 12 months after operation (Figure 7); and, (3) the one recent study reporting highly quantitative specific “percent diameter stenosis” values at 6 months (POEM study, Table 6).

Of the 17 CABG and 28 OPCAB studies reviewed (3368 and 2743 patients, respectively) only four were multicenter studies, 12 included angiographic follow-up at 6 months, five reported quantitative coronary angiography, three used an independent core angiographic laboratory, and only one study reported percent average diameter stenosis for both conventional CABG and OPCAB.^{1-6,12-49}

Only one study (single-center, single surgeon)³¹ of a total of 12 reporting angiographic patency results at 6 months showed the same 100% patency rate as was observed in the U-Clip study (Figure 6).^{2,5,32-39,49} All other available studies at the same 6-month follow-up period reported occlusion rates of between 1.5% and 10%. Study sample sizes ranged from 38 to 452 patients, and the overall average patency rate for all 12 studies was

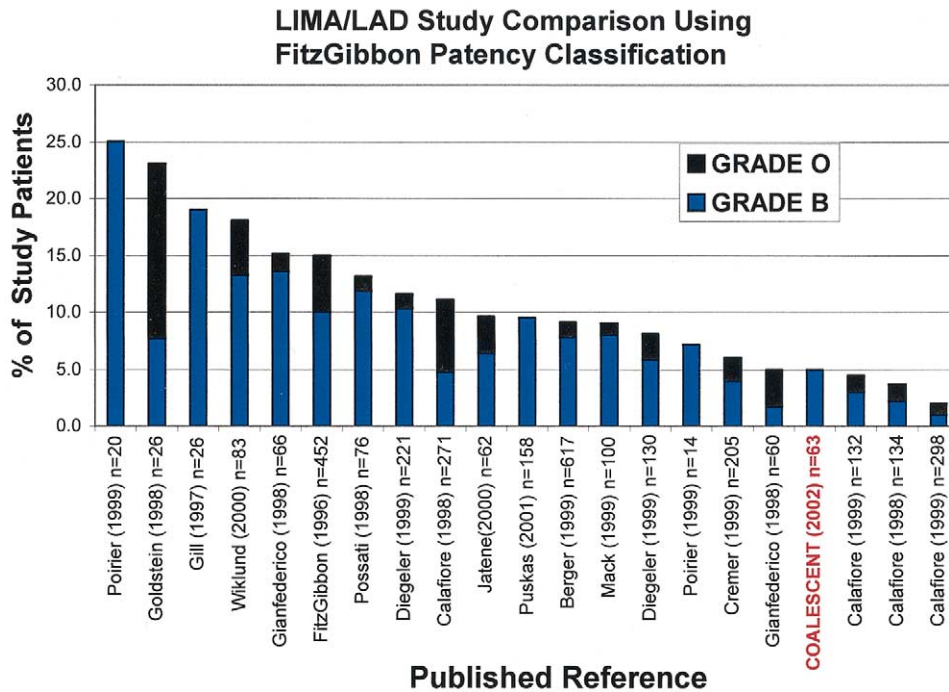


Figure 7. Studies reporting results by use of FitzGibbon patency classification scale.

the same 95% reported by FitzGibbon⁵ in the largest single study.

On the more quantitative FitzGibbon scale, there were three reports³⁵⁻³⁷ out of 20 other studies reporting Fitzgibbon scores that were marginally better than those observed in this U-Clip study (Figure 7).^{5,35-48} However, these three studies reported the observation of total occlusions not experienced in the U-Clip study.

Finally, when the results are compared with the most quantitative study available, the POEM study³⁵ (Table 6), a significant improvement in overall patency and average percent diameter stenosis (calculations shown in Figure 5) using the U-Clip device is evident. The POEM trial represents an example of the next generation of anastomotic clinical study. It was a multicenter study of on- and off-pump CABG that used an independent core angiographic laboratory [Cardiovascular Research Foundation (CRF)] that used QCA, ensuring representative sampling of surgical skill and nonbiased review of angiographic data. CRF reported an average of 23% and 24% average percent diameter stenosis (63% 6-month angiographic follow-up) in the POEM study for CABG and MIDCAB, respectively (Table 6). This average percent diameter stenosis value (a calculation favored by CRF) compares the size of the anastomosis with the average of the LITA immediately proximal to the anastomosis and the LAD immediately distal to the anastomosis. The U-Clip study by comparison showed anastomotic stenosis as a percentage of average LITA and LAD

TABLE 6. Quantitative angiographic results: comparison to POEM* study

	POEM CABG (n = 70)	POEM MIDCAB (n = 103)	Coalescent (n = 63)
Reference			
LITA (mm)	2.3 ± 0.5	2.4 ± 0.5	2.1 ± 0.5
LAD (mm)	1.9 ± 0.4	1.8 ± 0.3	1.9 ± 0.5
MLD (mm)	1.8 ± 0.6	1.9 ± 0.0	2.0 ± 0.5
Patency (%)	95.7	95.1	100.0
% Diameter stenosis	24 ± 24	23 ± 27	-2.3 ± 19

*Patency, Outcomes, Economics of MIDCAB, as reported by the CRF <http://www.tctmd.com/expert-presentations/>

diameter to be -2.3%. This result is significantly superior to what was reported in the POEM study ($P < .001$).

Limitations of this study include a modest sample size and a nonrandomized patient population selected for conformance to prespecified inclusion and exclusion criteria. Given these limitations, however, the results appear to support the hypothesis that an interrupted technique results in a superior vascular anastomosis. This is believed to be due to two primary factors. Firstly, increased anastomotic compliance and flow rate resulting from the interrupted technique, and, secondly, the elimination of the potential for purse-string and puckering effects encountered when attempting to achieve hemostasis by use of a continuous piece of conventional suture.⁴⁷⁻⁴⁹ An additional advantage of the

U-Clip is the availability of a fresh, sharp needle with each clip, decreasing target vessel needle injury, especially in the less than ideal target.

We believe that it is important to carefully and objectively assess achieved anastomotic quality rather than make the potentially incorrect assumption of a 96% patency rate (shown by the Cleveland Clinic when an interrupted technique is used). This is best done with objective 6- to 12-month postoperative QCA as a benchmark. This is consistent with the adoption of QCA as the standard of care by the American Heart Association⁵⁰ and the establishment of QCA as a requirement by the FDA for evaluation of any new interventional and surgical anastomotic device.

To date, more than 100,000 interrupted coronary anastomoses have been completed worldwide by use of the U-Clip device. This possible trend toward returning to the interrupted suture technique will allow further assessment of the impact on both individual graft patency and the continued viability of surgical revascularization.

In relationship to cost, any significant increase in procedure cost in this era of managed care would be of concern. After an initial learning curve, 8 to 10 clips are typically used per anastomosis for a cost of approximately \$150. Suture costs per anastomosis vary widely, depending on several factors, including technique (interrupted versus continuous), suture material (silk, polypropylene, etc), needle configuration, hospital volume, and overall group purchasing organization affiliation. Silk sutures, often used for the interrupted technique, vary in price from \$7 to \$15 per strand, yielding a price per anastomosis ranging from \$84 to \$180 (assuming 12 sutures per anastomosis).⁵¹

Polypropylene sutures, most frequently used in a single-stranded continuous technique, vary in price from \$15 to \$120, yielding a similar price per anastomosis.

In 1998 average cost of CABG was reported as \$44,820.⁵² With this used as a benchmark, conversion of three distal anastomoses from suture to the U-Clip anastomotic device would result in an incremental procedural cost of \$405 (less than 1% of overall procedural cost) at worst and would be cost neutral at best.

Conclusions

Use of the U-Clip device to facilitate an interrupted anastomosis resulted in excellent and unequaled long-term graft patency and anastomotic quality as objectively assessed by use of quantitative, 6-month postoperative angiographic analysis. These results were obtained in spite of the variables associated with a multicenter, multisurgeon, multitechnique study that included the learning curve associated with the use of a new device.

The results of this study show that the U-Clip device is capable of facilitating the use of the interrupted technique in

both on- and off-pump CABG procedures and, as such, represent an important next step in the effort to continuously improve the quality of cardiovascular anastomosis.

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Discussion

Dr Erik W. Jansen (Utrecht, Netherlands). This is an interesting multicenter trial on an innovative coronary artery, actually a general vascular, anastomosis technique. On average, 11.8 self-closing clips were used to create the LITA-to-LAD anastomosis, requiring a mean anastomosis time of 10 minutes and a minimum of 3 minutes. Most were done on OPCAB. So this is really a smooth procedure. That is very good. There were only two conversions, no reoperations for bleeding. What was the rate of extra sutures or clips for hemostasis?

The quality of the anastomosis is well studied by use of the current standards of FitzGibbon, TIMI, and POEM in angiography in 77% of patients. The 6-month patency rate as a standard is good, 94% FitzGibbon grade A, and a favorable percent diameter stenosis. This compares with the patency in all recent off-pump trials.

There is little intravascular nitinol, thus low thrombogenicity. Did the patients receive any antithrombotic medication?

The technique looks very attractive and simple. Basically, it is a classic interrupted technique creating a wide patency, as you showed. Clear advantages are demonstrated. This is an anastomosis technique based on the surgeon's skill that is highly compliant to vessel structure and presentation, and an interrupted suturing technique that is highly compliant to local calcification and a