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Six-Month Angiographic Evaluation of Beating-Heart Coronary Arterial Graft Interrupted Anastomoses Using the Coalescent U-CLIP Anastomotic Device: A Prospective Clinical Study

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ABSTRACT

Background: Interrupted suture technique avoids the "purse string" and puckering effects frequently seen with continuous suture techniques and should represent the standard of care in the creation of high-quality vascular anastomoses. This clinical study evaluated the safety and effectiveness of a self-closing surgical clip (Coalescent Surgical U-CLIP Anastomotic Device [U-CLIP]) designed to facilitate this interrupted technique. Left internal mammary artery (LIMA) to left anterior descending (LAD) coronary bypass grafting was studied.

Methods: Eighteen patients meeting inclusion criteria were enrolled (October 2000 through September 2001) into this prospective study. Anastomoses were performed using a beating-heart median sternotomy procedure (off-pump coronary artery bypass) in 17 cases (94%) and a minimally invasive beating-heart procedure (minimally invasive direct coronary artery bypass [MIDCAB]) in one case (6%). Six-month follow-up was completed on 18 patients (100%), with angiograms performed on 17 patients (94%) at a mean of 179 days (range, 168-191 days). Qualitative and quantitative angiographic assessment was performed by an independent core laboratory.

Results: The U-CLIP was used for 18 LIMA-to-LAD interrupted anastomoses without the requirement for knot tying or suture management and with no device-related morbidity or mortality. Mean LIMA-to-LAD anastomosis time was 8.6 minutes (range, 5-14 minutes). All anastomoses were FitzGibbon grade A at 6 months postprocedure. Quantitative analysis showed mean luminal diameters proximal to the anastomosis of 2.32 mm, at the anastomosis of 2.25 mm, and immediately distal to anastomosis of 1.99 mm. The average ratio of anastomosis to LAD diameter was 1.17 (range, 0.93-1.93). Anastomotic stenosis as a percentage of average LIMA/LAD diameter was a *negative* 4.2%, comparing favorably with the 23% to 24% reported in the POEM (Patency, Outcomes, Economics of MIDCAB) study.

Conclusions: The interrupted technique, facilitated by a self-closing anastomotic clip, yielded 6-month follow-up and angiographic results that compared favorably with results of other published studies.

INTRODUCTION

The cardiovascular surgery group at St. Joseph's Hospital in Phoenix, Arizona, performs surgery on a total of 1500 hearts annually, with the primary investigator of this study (M.P.C.) completing approximately 400 heart surgeries (25%) per year. Beating-heart technique was adopted in our practice in 1997 and we have performed approximately 2000 beating-heart procedures over the past 5 years. Beating-heart surgery now represents roughly 80% of our routine practice.

St. Joseph's Hospital was 1 of 6 centers participating in the Coalescent U-CLIP Anastomotic Device Study. Ohio State University, one of the other participating centers, has recently published their early results [Ono 2002]. At St. Joseph's, we completed 17 (27%) of the 63 total angiograms obtained at 6-month follow-up. In contrast to the complete multicenter study in which a wide variety of techniques were used, our study used exclusively beating-heart technique, and for this reason, it is instructive to evaluate our results separately.

The relentless pressure toward minimally invasive revascularization methods and the emergence of beating-heart surgery in particular have resulted in an increased focus on anastomotic patency and quality. This focus can be seen in the significant increase in the number of papers addressing the issue of anastomotic quality (Figure 1). The objective of this definitive investigational study was to submit data to the US Food and Drug Administration (FDA) that would formally establish the safety and effectiveness of the U-CLIP when used to facilitate an "interrupted" suture technique in distal coronary artery bypass grafting procedures using a variety of surgical approaches and techniques. Feasibility of this device in both animal and human studies has been previously reported [Hill 2001, Ono 2002], and it is estimated that as of June 2002 the device had been used in more than 50,000 anastomoses.

An interrupted suture technique has long been believed to represent a superior approach to microvascular anastomosis

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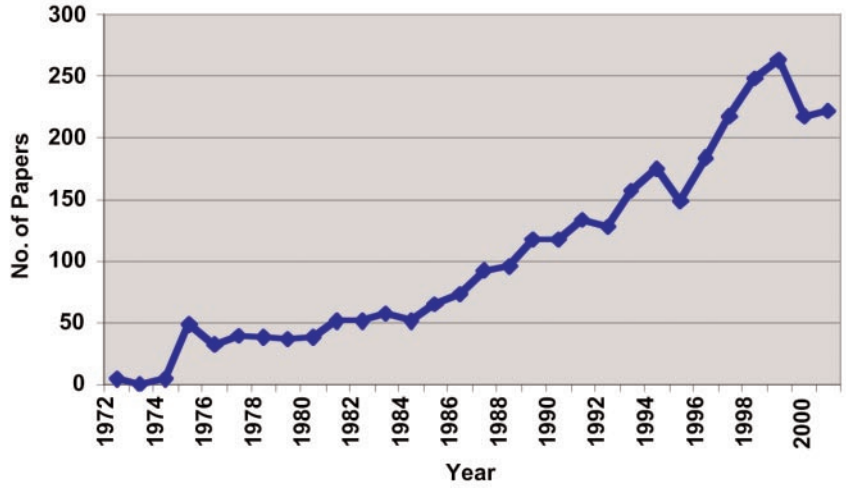

Figure 1. Published references to "patency" or "quality" and "CABG." The number of papers that come up each year from the Medline search: "(Patency OR Quality) AND CABG."

because of the potential for improved flow rates through increased compliance and the elimination of the "purse string" and puckering effects encountered when a continuous piece of conventional suture is used in an attempt to achieve hemostasis [Schlechter 1994, Lytle 2000, Baguneid 2001, Tozzi 2001]. The impact of an interrupted suture technique on anastomotic quality was persuasively demonstrated through early work completed at the Cleveland Clinic by Floyd Loop and Bruce Lytle et al [Loop 1979, Loop 1986]. In these early studies, Loop reported 96% LIMA-to-LAD arterial graft patency at 6 months, with 98% and 96% arterial graft patency at 1 and 10 years, respectively, using an interrupted technique. Although Berger et al [1999], for example, has reported early patency of >98% at 10.8 days using a continuous suture technique, other investigators including FitzGibbon et al [1996] have reported patency rates of 95%, 91%, and 80% at up to 6 months, 2.5 years, and >5 years, respectively. These published studies using the continuous suture technique, and many others completed subsequent to Loop and Lytle's work, have not matched the original Cleveland Clinic results. Consequently, it may well be inappropriate to assume that medium- and long-term results obtained using the more expedient continuous suture technique will compare with the often-quoted Cleveland Clinic results obtained using interrupted suture technique.

Adaptation of the interrupted technique has clearly been inhibited by the increased procedural complexity and duration associated with the concomitant requirements for suture management and knot tying. The 2 questions we at St. Joseph's set out to answer through this study were: (1) How effectively would the Coalescent U-CLIP facilitate an interrupted technique? and (2) Would these results, using the interrupted technique, differ from published/presented data using conventional continuous suture methods? The U-CLIP self-closing clip has the advantage of being individually applied via a standard curved suture needle and therefore appears to be potentially useful in a broad range of anastomotic applications, including a variety of valve and other cardiovascular procedures.

MATERIALS AND METHODS

The study device, the Coalescent Surgical U-CLIP anastomotic device (U-CLIP) (Coalescent Surgical, Sunnyvale, CA) (Figure 2) consists of a self-closing surgical clip attached to a conventional surgical needle via a flexible member. The device, fabricated from the "shape-memory alloy" nitinol, was designed to provide an alternative to conventional suture and surgical clips in a variety of tissue approximation and anastomosis applications. The U-CLIP is placed via a conventional needle with the use of a standard needle driver and does not require a custom clip applier. Suture-like characteristics allow precise tissue positioning and alignment, and the self-closing clip technology eliminates the requirement for knot tying and

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

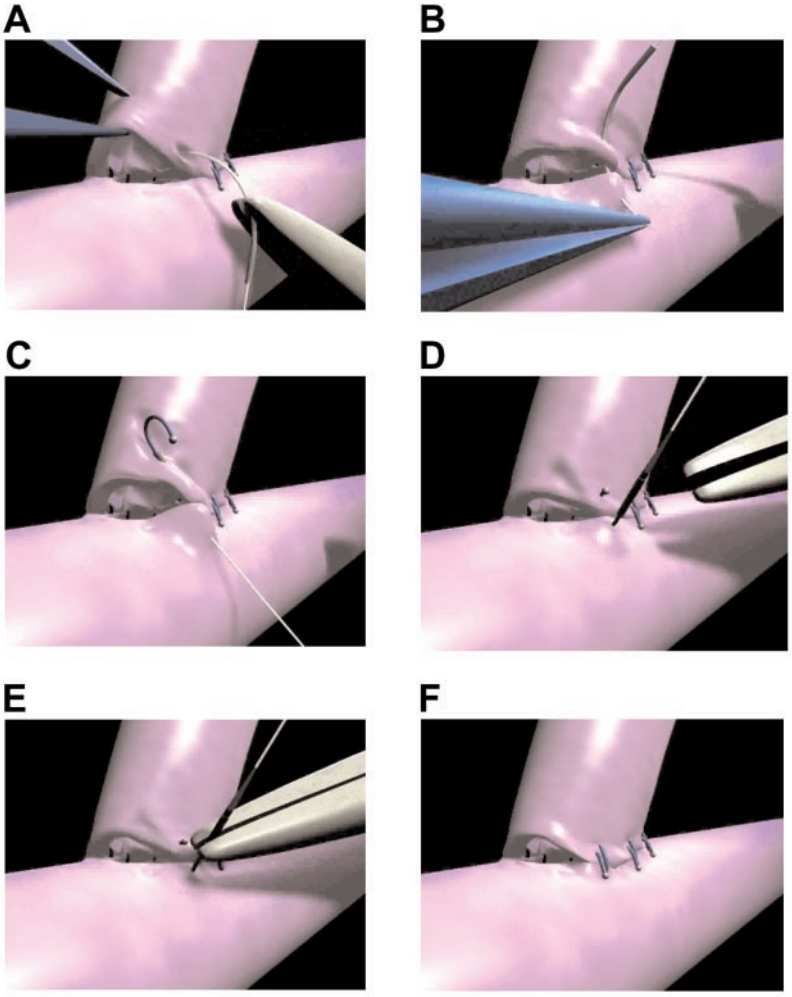

Figure 3. Placement of U-CLIP. A, Needle placed through graft. B, Needle pulled through artery. C, Clip being pulled into place. D, Clip placed in desired location. E, Actuation of clip release: U-CLIP closure and removal of needle and flexible member. F, Finished anastomosis: self-closing clip traps tissue.

suture management. In addition, the U-CLIP provides the surgeon with a new, sharp needle with each clip.

The U-CLIP consists of 4 basic components: a self-closing clip, a release mechanism, a flexible member, and a needle (Figure 2◎). Surgical application consists of (1) piercing the desired tissue (graft and native artery) with the needle (Figures 3A and 3B◎), (2) placement of the clip via pulling the flexible member and release mechanism through the tissue (Figures 3C and 3D◎), and (3) closure of the clip and release of the delivery mechanism via the application of pressure (Figures 3E and 3F◎). Once released, the needle and flexible member are removed and discarded. Anastomoses are formed in the usual manner, with a number of clips applied in a circular fashion around the anastomotic site (Figure 3D◎). Individual placement of U-CLIPS results in the desired "cobra-head" appearance of the completed anastomosis (Figure 4◎).

Study inclusion and exclusion criteria were adopted from the joint American College of Cardiology (ACC) and American Heart Association (AHA) practice guidelines for coronary artery bypass graft surgery [1991] and coronary angiography [1987]. An attempt was made to exclude patients with LAD vessels <1 mm in diameter. Intraoperative exclusion criteria included contraindications to use of the LIMA (damage during preparation) or inadequate free LIMA flow (<60 cc/minute, approximately) See the Appendix for a more complete description of exclusion criteria.

A total of 6 clinical sites and 8 principal investigators participated in the overall study. Investigators were allowed to use either arrested-heart or beating-heart technique 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 prior to using the device clinically. This porcine procedure was the only training that each investigator received prior to enrolling clinical patients. Patients meeting all inclusion criteria (Appendix) and giving informed consent were enrolled into the study. The study device was used to complete a LIMA-to-LAD interrupted anastomosis. Flow rate prior to closure was obtained via ultrasound flow probe. More than 20 separate case report forms were completed for each patient per study protocol.

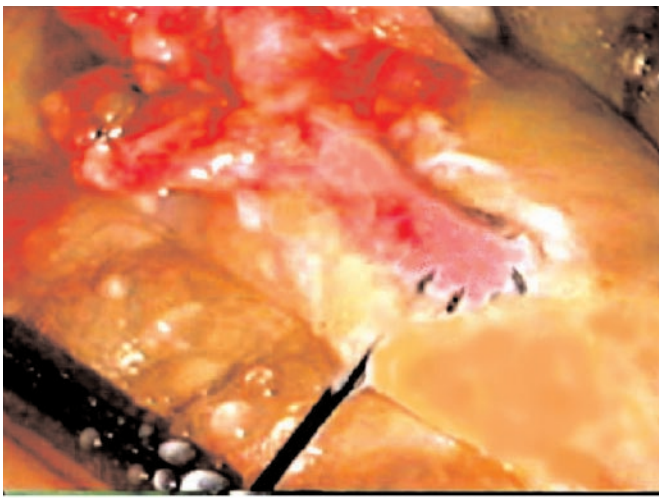

Figure 4. Completed left internal mammary artery–to–left anterior descending coronary artery anastomosis with "cobra head" appearance.

Patients were managed postoperatively in the usual and customary fashion with no administration of additional anticoagulation therapy. All patients were followed up at approximately 2 weeks and then again at 6 months after surgery.

The use of quantitative angiographic follow-up at a minimum of 6 months postoperation was key to the objective evaluation of revascularization results. Quantitative angiographic analysis, or quantitative coronary angiography (QCA), including the measurement of proximal and distal LIMA graft internal lumen dimensions, resulting minimum luminal diameter (MLD) at the anastomotic site, and the native LAD dimensions, completed by an independent core lab, continues to represent the gold standard for objective assessment of anastomotic patency and overall revascularization quality. This procedure has been established as the standard of care by the AHA and has been completed in all recent interventional and surgical device studies [ACC/AHA 2002] and has been established as a requirement by the US FDA for evaluation of any new interventional and surgical anastomotic device.

The core angiographic laboratory at Stanford University Medical Center, under the direction of Dr. Alderman, independently evaluated all 6-month LIMA-to-LAD anastomoses. Dr. 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 calculations described below.

RESULTS

Demographics

A total of 21 patients consented to participate and were provisionally enrolled into this study at St. Joseph's Hospital. Three of these 21 patients were found interoperatively to have inadequate LIMA grafts as defined by the study protocol (<60 cc estimated flow per minute). The remaining 18 treated patients comprised 18 males and no females and had a mean age of 64 years (range, 49-81 years) and a mean body mass index of 29.3 (range, 21.2-37.6) (Table 1). These 18 patients were enrolled in the prospective study and followed postoperatively for the required 6-month period. One patient was excluded because the surgeon and the patient's cardiologist determined that a postoperative 6-month angiogram entailed an unreasonable risk of complications.

Intraoperative Summary

LIMA-to-LAD interrupted anastomoses were completed using the U-CLIP in 18 total procedures; 17 (94%) were beating-heart median sternotomy procedures (off-pump coronary artery bypass), and 1 (6%) was a minimally invasive beating-heart procedure (minimally invasive direct coronary artery bypass [MIDCAB]).

Mean LIMA-to-LAD anastomosis time was 8.6 minutes (range, 5-14 minutes) with a clear learning curve (last 6 cases averaged 7.7 minutes). All 18 grafts were patent and none were found to be leaking intraoperatively. The average number of U-CLIPS used was 14.1, with a minimum of 10 and a maximum of 18. Average length of intensive care unit stay was 47 hours and average hospital stay was 5 days (Table 2).

One mild perioperative myocardial infarction occurred in 1 patient. This adverse event was unrelated to the study device. There were 7 cases of postoperative arrhythmia consisting of paroxysmal atrial fibrillation and intermittent sinus bradycardia or ventricular tachycardia; all were successfully medically treated and were unrelated to the U-CLIP. There was a single case of postprocedure urinary retention. There were 2 cases of arrhythmia, 1 case of transient ischemic attack, and 1 case of pleural effusion reported during the 6-month follow-up period. Again, none of these adverse events were related in any way to the use of the study device.

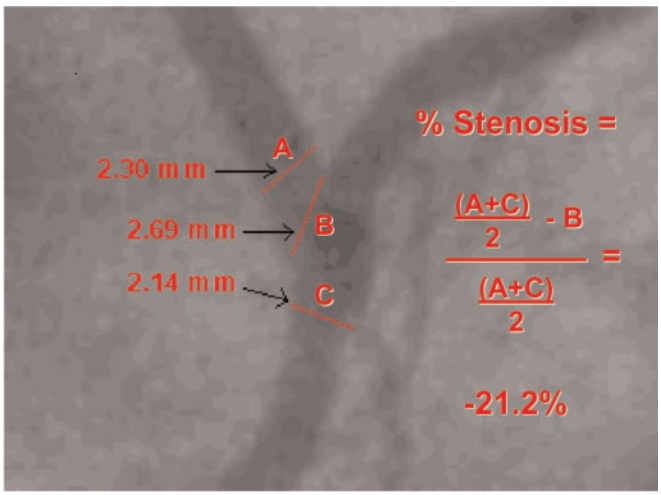

Figure 5. Anastomotic dimensions determined during QCA: A, portion of left internal mammary artery graft immediately proximal to anastomosis; B, anastomosis dimension; C, native left anterior descending coronary artery immediately distal to anastomosis site. Calculation for average percent diameter stenosis is shown.

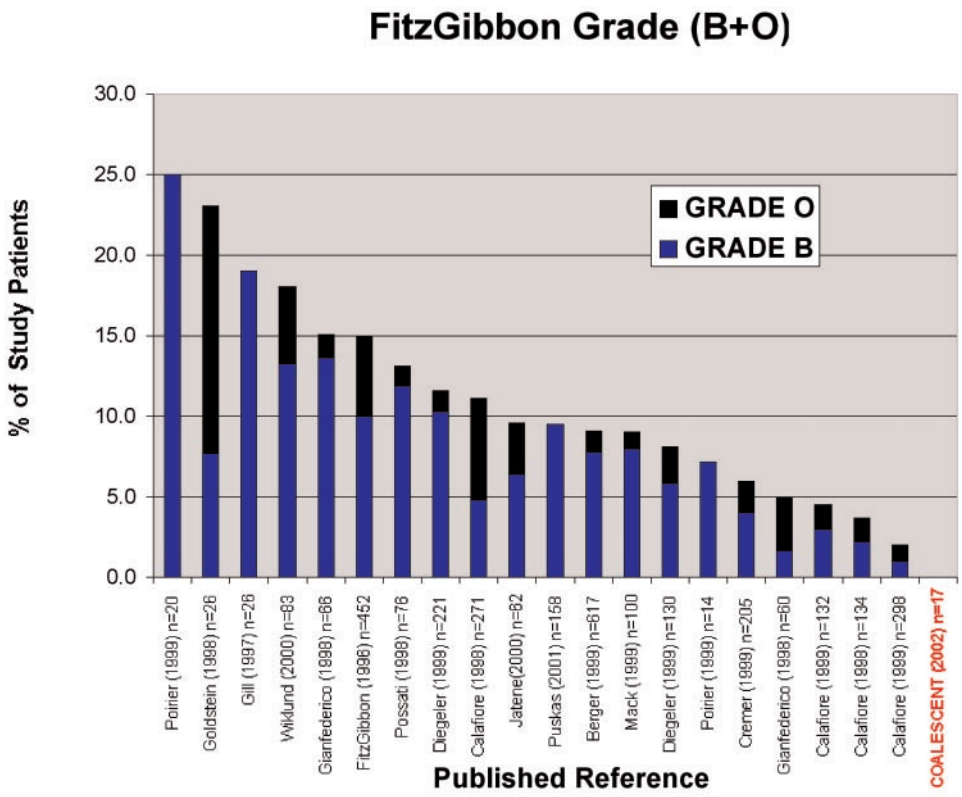

Figure 6. Studies reporting results using the FitzGibbon patency classification scale.

Core Laboratory Analysis

The Core Angiographic Laboratory at Stanford used both qualitative and quantitative methods to evaluate each anastomosis. Qualitative methods included estimates of TIMI (thrombolysis in myocardial infarction) flow grade and general assessments of patency. Quantitative techniques, which were more definitive, included assignment of a FitzGibbon score that included not only the quality of the anastomosis (greater or less than 50% stenosed) but also quality and patency of the graft. Finally, most quantitative analyses were completed by measuring the luminal diameters of the LIMA 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, and Economics of MIDCAB (POEM) study (see discussion below).

All 17 LIMA-to-LAD anastomoses (100%) were found to be patent at follow-up (Table 3). The core angiographic laboratory graded all 17 (100%) of the 6-month postoperative angiograms as FitzGibbon grade A (<50% stenosis of either graft trunk or anastomosis compared to LAD). There were no FitzGibbon grade B (>50% stenosis) or grade O (occlusions) results observed. Detailed quantitative analysis (n = 15) showed mean lumen diameters of the LIMA proximal to the anastomosis of 2.32 mm, at the anastomosis of 2.25 mm, and in the LAD distal to the anastomosis of 1.99 mm. The average ratio of the anastomosis to the LAD diameter was 1.17 (range, 0.93-1.93). Anastomotic "stenosis" as a percentage of average left internal thoracic artery (LITA)/LAD diameter was *negative* 4.2%. All 17 cases were graded TIMI grade 3.

Table 1. Patient Demographics

Age, mean ±SD (range), y	64.4 ± 9.7 (49-81)
Male/female, n	18/0
History of myocardial infarction, n (%)	7 (39%)
Body mass index, mean ± SD (range), kg/m^2	29.3 ± 4.0 (21.2-37.6)

DISCUSSION

Results from this study are best compared with studies reporting quantitative FitzGibbon scores between 6 and

Table 2. Perioperative Results*

No. of patients	n = 18
Time for anastomosis, min	8.6 ± 2.7 (5-14)
No. of clips	14.1 ± 2.5 (10-18)
Graft flow, mL/min	128.1 ± 95.5 (19-360)
Length of ICU stay, h:min	47:14 ± 1:13 (6:25-94:44)
Length of hospital stay, d:h	4:24 ± .06 (2:14-7:14)

*Data are expressed as mean ± SD (range). ICU indicates intensive care unit.

Table 3. Quantitative Angiographic Analysis Results*

Patient	Days Post-Op	FitzGibbon Score	FitzGibbon Disease Score	TIMI Flow	LIMA Body	LIMA Proximal	Anastomosis	Distal Distal LAD	Anastomosis:LAD Ratio	Reference Diameter	Diameter Stenosis
1	177	A	I	3	NA	NA	NA	NA	NA	NA	NA
2	168	A	I	3	3.39	2.46	2.6	2.81	0.93	2.64	1.3%
3	184	A	I	3	2.3	1.71	1.54	1.17	1.32	1.44	–6.9%
4	177	A	I	3	2.23	1.96	2.01	1.04	1.93	1.5	–34.0%
5	181	A	I	NA	1.9	1.94	NA	NA	NA	NA	NA
6	178	A	I	3	2.32	2.08	2.24	1.92	1.17	2.00	–12.0%
7	183	A	I	3	2.75	2.33	2.08	2.03	1.02	2.18	4.6%
8	168	A	I	3	2.02	1.72	1.39	1.22	1.14	1.47	5.4%
9	191	A	I	3	2.19	2.27	1.9	2.01	0.95	2.14	11.2%
10	189	A	I	3	2.56	2.49	2.39	2.32	1.03	2.41	0.6%
11	182	A	I	3	2.82	1.94	2.33	1.84	1.27	1.89	–23.3%
12	180	A	I	3	3.43	2.53	2.55	2.27	1.12	2.4	–6.3%
13	162	A	I	3	3.39	3.94	3.8	2.21	1.72	3.08	–23.6%
14	176	A	I	3	2.84	2.18	2.08	2.07	1.00	2.13	2.1%
15	175	A	I	3	3.22	2.91	2.52	2.61	0.97	2.76	8.7%
16	177	A	I	3	2.46	1.97	1.93	1.84	1.05	1.91	–1.3%
17	175	A	I	3	2.41	2.74	2.33	2.49	0.94	2.62	10.9%
Mean	178.7	17/A	17/I	16/3	2.64	2.32	2.25	1.99	1.17	2.17	–4.2%
Minimum	168				1.9	1.71	1.39	1.04	0.93	1.44	–34.0%
Maximum	191				3.43	3.94	3.8	2.81	1.93	3.08	11.2%

*TIMI indicates thrombolysis in myocardial infarction; LIMA, left internal mammary artery; LAD, left anterior descending coronary artery; NA, not assessable because of inadequate opacification for quantitative analysis.

12 months postoperatively (Figure 6◎) and with the only other study reporting highly quantitative coronary angiography (QCA) results at 6 months (POEM Study, Table 4). Our study sample size of 17 angiograms compares with the sample size in some of the smaller studies reported (Poirier, n = 14 and n = 20 and Gill and Goldstein, n = 26; Figure 6◎).

On the quantitative FitzGibbon scale, there have been no reports out of the 20 other studies reporting FitzGibbon scores that demonstrated better results than those observed in the current U-CLIP study (Figure 6◎) [Gill 1997, Goldstein 1998, Possati 1998, Berger 1999, Diegler 1999, Mack 1999, Poirer 1999, Jatene 2000, Puskas 2001]. Study results of 100% FitzGibbon grade A anastomotic patency, with no grade B or grade O, have not been reported prior to this study.

The results of this study compared with those of the POEM study [Mehran 2001] (Table 4) show a significant improvement in overall patency and average percent diameter stenosis (calculations shown in Figure 5◎) using the U-CLIP. The POEM trial represents the most quantitative anastomotic clinical study available. It comprised a multicenter study of on- and off-pump CABG that used QCA conducted by an independent core angiographic laboratory (Cardiovascular Research Foundation [CRF]), assuring representative sampling of surgical skill and nonbiased review of angiographic data. CRF reported an average of 23% and 24% diameter stenosis in the POEM study for CABG and MIDCAB, respectively (Table 4). This CRF-generated average percent diameter stenosis value compares the size of the anastomosis with the average of the LIMA immediately proximal to the anastomosis and the LAD immediately distal to the anastomosis. Our U-CLIP study, in comparison, showed anastomotic stenosis as a percentage of average LIMA and LAD diameter to be a *negative* 4.16%. This result is significantly superior to that reported in the POEM study ($P < .001$).

Results for the overall study were presented by Dr. Wolf at the May 2002 American Association of Thoracic Surgeons (AATS) meeting. All 63 (100%) of the LIMA-to-LAD

Table 4. Quantitative Angiographic Results: Comparison to POEM Study*

	POEM CABG (n = 70)	POEM MIDCAB (n = 103)	Caskey et al (n = 17)
Reference			
LIMA, mm	2.3 ± 0.5	2.4 ± 0.5	2.3 ± 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.	2.2 ± 0.5
Patency, %	95.7	95.1	100.0
Diameter stenosis, %	24 ± 24	23 ± 27	–4.2 ± 19

*POEM indicates Patency, Outcomes, Economics of MIDCAB study, as reported by the Cardiovascular Research Foundation (http://www.tctmd.com/expert-presentations/multi-slide.html?product_id=182); CABG, coronary artery bypass graft; MIDCAB, minimally invasive direct coronary artery bypass; LIMA, left internal mammary artery; LAD, left anterior descending coronary artery; MLD, minimum luminal diameter.

Table 5. Core Angiography Lab Results for Entire Study*

Site	TIMI Flow 3	TIMI Flow 2	TIMI Flow 1	Patency, %	FitzGibbon Grade A	FitzGibbon Grade B	FitzGibbon Grade O	Anastomosis:LAD Ratio	Average % Stenosis at Anastomosis
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 (95%)	3 (5%)	0 (0%)	1.14	–2.3 ($P < .1$)

*TIMI indicates thrombolysis in myocardial infarction; LAD, left anterior descending coronary artery; DSH, Desert Samaritan Hospital, Mesa, Arizona (Dwight Lundell, MD, and Allen Raczkowski, MD); OSU, Ohio State University, Columbus, Ohio (Randall Wolf, MD); SJH, St. Joseph's Hospital, Phoenix, Arizona (Michael Caskey, MD); WASH, Washington Hospital Center, Washington, DC (Mercedes Dullum, MD); UNMC, University of Nebraska Medical Center, Omaha, Nebraska (Arthur Hill, MD); KFH, King Fahad Hospital, Riyadh, Saudi Arabia (Nan Wang, MD).

anastomoses were found to be patent at follow-up (Table 5). 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 compared to LAD) and only 3 (5%) as FitzGibbon grade B (>50% stenosis), including 1 kinked LIMA graft unrelated to the anastomosis. There were no occlusions (FitzGibbon grade O) observed. Detailed quantitative analysis (n = 57) showed mean lumen diameters of the LIMA 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. The average ratio of the anastomosis to the LAD diameter was 1.14 (range, 0.45 to 1.93). Anastomotic stenosis as a percentage of average LITA/LAD diameter was *negative* 2.26%, excluding the one FitzGibbon grade B result that could not be quantified because of competing native-vessel flow. The overall study results were very comparable to off-pump results obtained at St. Joseph's Hospital.

These results strongly suggest that an interrupted technique does in fact result in a superior coronary anastomosis. Two separate reasons for this observation are likely. The first is that an interrupted technique provides increased anastomotic compliance and flow rate. The second reason is the elimination of the classic purse string and puckering effect frequently encountered when using a continuous piece of conventional suture to obtain the necessary hemostatic vascular connection [Young 1978, Shioi 1984, Gerdisch 2002]. The U-CLIP has an additional advantage in that it provides the surgeon with a fresh, sharp needle with each clip. This feature clearly decreases the probability of target-vessel needle injury. All of these factors have been known to be of critical importance in microvascular surgery and their importance increases as referral patterns necessitate surgery on increasingly smaller target coronary arteries.

We believe that it is important to objectively assess anastomotic quality obtained in daily practice as opposed to making the assumption that individual results obtained using a continuous piece of suture automatically equate to the 96% patency rate for interrupted technique shown by the Cleveland Clinic. Postoperative quantitative angiographic analysis at 6 to 12 months clearly represents the benchmark for this purpose.

CONCLUSIONS

Our experience at St. Joseph's Hospital with the Coalescent U-CLIP Anastomotic Device was entirely consistent with that of the larger multicenter study, including the observation of superior anastomotic quality as objectively assessed by the independent core angiographic laboratory at Stanford University Medical Center. We found the clip easy to use, and the elimination of requirements for knot tying and suture management enabled an interrupted distal anastomosis to be completed in the same or less time than is commonly required with a single running stitch. The anastomotic results obtained in this study strongly support the hypothesis that an interrupted technique provides a significantly superior outcome.

APPENDIX

Exclusion Criteria

Preoperative Exclusion Criteria

- Severe cerebrovascular disease, including history of stroke within 1 month
- History of renal insufficiency (serum creatinine level >2 mg/dL)
- Active gastrointestinal bleeding
- Active infection or fever (>38.3°C) that may be caused by infection
- Short life expectancy (<2 years) as a result of cancer or pulmonary, hepatic, or renal disease
- Significant anemia (hemoglobin level <8.0 g)
- Severe, uncontrolled systemic hypertension (systolic pressure >240 mm Hg within 1 month)
- Severe electrolyte imbalance
- Documented anaphylaxis during previous exposure to angiographic contrast media
- Congestive heart failure
- Severe systemic disease

- History of pericarditis, median sternotomy, or chest irradiation
- Uncontrolled diabetes (2 glucose levels >350 mg/dL within 7 days)
- Bleeding diathesis
- Vasculitis
- History of intravenous drug use within prior year
- Participating in another investigational protocol
- Unwilling or unable to comply with any protocol requirements

Intraoperative Exclusion Criteria

- Inadequate estimated LITA flow
- Small LAD size at anastomotic site (<1 mm)
- Inadequate or damaged LITA
- Severe intramyocardial LAD (off-pump cases)
- Other presenting complications prohibiting use of either LITA or LAD
- Unexpected findings of any intraoperative exclusion
- Unexpected findings creating an unreasonable intraoperative risk or an increased probability of postoperative complications

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REVIEW AND COMMENTARY

1. Editorial Board Member JZ39 writes:

I liked the paper, but had some concerns about patient selection. This device seemed to be used only in rather plump juicy LADs and LIMAs. As such, it is not necessarily randomized or applicable to a broad cross-section of potential CABG patients. It would be nice for them to expand on how they selected these patients.

Authors' Response by Dr. Caskey:

The LAD and LIMA diameters as shown in Table 3 and Table 4 did not differ from those reported in the POEM study nor do they differ significantly from what is typically reported in the literature. Study exclusion criteria included LAD diameters less than 1.0 mm. We have added an Appendix that more completely describes the study exclusion criteria.

2. Editorial Board Member YT31 writes:

QCA for different anastamotic techniques is lacking in the literature and this paper provides some of that evidence.

a) A weakness of the paper is that the QCA comparison is historical rather than part of the prospective study. Although comparison to the POEM study is good and necessary for this study, a strength would have been blinded review of comparable groups by the same lab.
b) A commentary may be helpful because the Cleveland Clinic articles cited were not from a prospective study. In fact, several of these articles were more concerned with SVG patency, and the LIMA-to-LAD patency is uncertain from the criteria used in those studies. Although these factors do not severely detract from the substance this article, commentary on them could provide a fuller frame of reference for judging this paper.

Authors' Response by Dr. Caskey:

a) We generally agree with this observation. Although it would have been ideal, it was obviously not possible to arrange for blinded review of comparable groups by the same lab. We did do the next best thing, which was to consult with Dr. Roxana Mehran at the Cardiovascular Research Foundation, who was responsible for the analysis of the POEM results, to make certain that we were in fact analyzing our data in the exact same way as they did in their analysis.
b) We do not agree that the LIMA-to-LAD patency is uncertain from the criteria used in the cited Cleveland Clinic papers. The data are clear from these papers. However, the point of the citation was not to do a formal data comparison as was done with many of the other papers (reference charts provided in the paper) and especially with the POEM study. The reason for the citation was to provide historical perspective related to the interrupted suture technique and the issues associated with making the assumption of a 96% patency rate with continuous suture technique.

3. Editorial Board Member SG14 writes:

a) The study is underpowered by using only 17 anastomoses.
b) Section "Results": What is a "mild myocardial infarction"? Please specify.
c) "The myocardial infarction was entirely unrelated to the device." Please specify what it was related to.

Authors' Response by Dr. Caskey:

a) This is a report of only my portion of the total study. The total study (reported separately) consisted of a total of 63 6-month angiograms and was extensively reviewed in the discussion section of the manuscript.
b) A mild myocardial infarction was defined as a cardiac enzyme increase of greater than 3 times normal total creatine phosphate kinase (CPK) with an attendant greater than 5-fold increase in creatine kinase–isoenzyme MB (CK-MB) in the absence of electrocardiogram (ECG) changes, including specific Q-wave abnormalities. In this case, the total CPK enzyme increase at 24 hours was 1990 (compared with a total CPK limit of 1191) with an attendant increase in CK-MB to 113.5 (compared with a limit of 25). These enzyme increases occurred in the absence of ECG changes or attendant symptoms.
c) This myocardial infarction was thought to be a result of the patient's preexisting condition and the CABG procedure itself.