U-Clip Anastomoses in Coronary Artery Bypass Grafting: Initial Clinical Experience

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Richard J. Shemin, MD, Oz M. Shapira, MD, Rahul V. Pawar, MD, Yusheng Bao, MD, Umer Sayeed-Shah, MD, Harold L. Lazar, MD

Boston Medical Center, Boston, Massachusetts, USA

ABSTRACT

Background: Recent studies suggest that the U-Clip interrupted coronary artery anastomosis is superior to continuous suture. However, clinical experience with this device is limited.

Aim: To evaluate our initial clinical experience with the U-Clip technology.

Methods: Outcomes of 59 patients undergoing isolated coronary artery bypass grafting (CABG) using U-Clips (UCs) were compared to outcomes of 138 patients undergoing CABG using conventional sutures (Conv).

Results: The average number of distal anastomoses was similar in the groups (UC, 2.9; Conv, 3.2; P = .33). Also similar were the number of arterial grafts (1.6 versus 1.5, P = .4), percentage of sequential anastomoses (22% versus 12%, P = .058), and percentage performed off pump (27% versus 28%, P = .74). Cardiopulmonary bypass and aortic cross-clamp times were longer in the UC group (98 ± 27 versus 81 ± 20 minutes, P = .001; 63 ± 25 versus 54 ± 24 minutes, P = .028). Rates of operative mortality (UC, 1.69%; Conv, 0.7%), postoperative myocardial infarction (0% each), stroke (0% each), renal failure (2% versus 1.4%), and blood transfusion (53% versus 58%) were not statistically different. Average follow-up in 36 (61%) of UC patients was 5 ± 2 months (range, 1-7 months). One patient died from a non–cardiac-related cause. At the time of follow-up 90% of patients were in angina class I-II.

Conclusions: The U-Clip interrupted anastomosis technique is versatile and safe and is associated with excellent short-term outcomes.

INTRODUCTION

The coronary artery bypass graft (CABG) operation has matured into a reproducible and safe procedure. Major advances have provided the milestones to achievement of reliable clinical results, relieving angina and in selected cases prolonging life. The major technical maneuver during the procedure is the anastomosis.

The use of an arterial conduit, especially the anastomosis of the left internal thoracic artery to the left anterior descending coronary artery, has prolonged survival and reduced rates of reoperation and angina recurrence. Loop and colleagues at the Cleveland Clinic demonstrated the durability of this artery, its freedom from atherosclerosis, and 10-year patency rates of greater than 95% [Loop 1986]. The preferred technique for the surgical anastomosis has been interrupted sutures [Loop 1979, Loop 1986, Lytle 2000]. Fine silk was used to reduce the time spent for knot tying. Currently polypropylene monofilament suture is the dominant vascular anastomosis material, and the running anastomotic technique has become standard. The classical interrupted anastomosis is rarely used except for small-vessel anastomosis. Suture tying is time-consuming and an encumbrance, especially as we enter the minimally invasive and robotic era of cardiac surgery.

The novel Coalescent Surgical U-Clip anastomotic device was designed to facilitate an interrupted anastomosis without the need to tie sutures, thus producing a high-quality anastomosis. The device consists of a self-closing surgical clip attached to a conventional surgical needle via a flexible member. The device is fabricated from nitinol, which has the property of shape memory, allowing closure of the arms upon simple deployment (Figure). The standard needle allows the surgeon to use conventional needle drivers and preserves the ability to align tissue precisely. The self-closing after deployment eliminates knot tying and suture management. Thus the interrupted anastomotic technique is enabled by this technology.

This present study documents the clinical outcomes of a single surgeon's practice after a sudden, total adoption of the U-Clip for all CABG conduit anastomoses (proximal and distal).

METHODS

All CABG procedures performed with the aid of cardiopulmonary bypass employed heparin-coated circuits with a low-dose (1 mg/kg) heparin protocol. A single cross-clamp technique for both proximal and distal anastomoses was used. Standard cold crystalloid cardioplegia and topical cold saline provided myocardial protection. Off-pump CABG was performed with standard temporary proximal occlusion of the target coronary artery, exposure and stabilization with

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Address correspondence and reprint requests to: Richard J. Shemin, MD, Boston Medical Center, 88 East Newton St, Suite B-402, Boston, MA 02118, USA; 1-617-638-7350; 1-617-638-7228 (e-mail: richard.shemin@bmc.org).

The Coalescent U-Clip.

commercially available devices, and visualization enhancement with a mister blower.

Postoperative care was protocol driven and standardized with clinical pathways. All patients were treated with aspirin and atorvastatin calcium (Lipitor) postoperatively. Data elements were stored in a customized Society of Thoracic Surgeons database. Late follow-up was accomplished by contacting the patient and the referring physician.

Statistical analysis was performed with Statview (Abacus Concepts, SAS Institute, Cary, NC, USA) employing the χ^2 test for categorical variables and unpaired *t* tests for continuous variables.

Table 1. Patient Characteristics*

	U-Clips (n = 59)	Prolene (n = 138)	*P*
Age	64 ± 10	67 ± 10	.09
Male	68%	78%	12
No. of diseased vessels	2.6 ± 0.6	2.7 ± 0.5	.1
Ejection fraction	52 ± 12	48 ± 13	.037
Prior PTCA	8%	15%	.2
Prior stent	7%	8%	.77
CHF	10%	12%	.77
CCS stage, III/IV	63%/10%	58%/16%	.33
Prior CVA	5%	4%	.82

*PTCA indicates percutaneous coronary angioplasty; CHF, congestive heart failure; CCS, Canadian Cardiovascular Society; CVA, cardiovascular accident.

The cohort studied was the first 59 patients undergoing CABG with U-Clips (April 2002-December 2002) and the prior 138 CABG patients who underwent surgery before the U-Clip series began. An additional 45 patients had valve replacement procedures with CABG using U-Clips. These patients are not included in this report.

RESULTS

The characteristics of the 138 patients for whom anastomoses were performed with continuous running prolene sutures (7-0 and 8-0) and the 59 patients for whom U-Clips were used exclusively are presented in Table I. The only significant difference was a slightly better ejection fraction (48% versus 52%) for the non–U-Clip patients.

The operative data are presented in Table 2. The single cross-clamp time for the U-Clip group was 68 ± 17 minutes. The prolene group had a cross-clamp time of 57 ± 19 minutes (P = .03). The groups were similar in all other aspects. The off-pump patients were not included in the calculation of mean cross-clamp times and pump times. The rate of off-pump cases was similar in both groups (27% versus 26%). The average times to perform anastomoses were 10 minutes for a U-Clip distal anastomosis and 6 minutes for a running prolene anastomosis.

Clinical outcome data prior to hospital discharge did not differ for any studied variables (Table 3). The expected mortality for the prolene group was 3.1% with an observed mortality of 0.7%; the U-Clip group had an expected 3.2% mortality with an observed mortality of 2.0% (P = .53).

Postoperative complication rates (Table 4) were equally low in both groups. Blood transfusion amounts and reoperation rates for bleeding were 1.2 ± 1.7 units and 1.4% in the prolene group compared to 1.3 ± 1.5 units and 2% in the U-Clip group; neither result was statistically significant. In the prolene group 42% of patients did not require any transfusions compared to 47% in the U-Clip group (P = .48).

Of 3 perioperative deaths, 2 occurred in the prolene group. One patient died from multiorgan failure and 1 from systemic sepsis. The only death in the U-Clip group was due to a sudden pulmonary arrest leading to open-chest cardiac resuscitation, during which graft patency was confirmed.

Late follow-up periods for the U-Clip patients were 90% compatible with a range of 1 to 7 months (mean, 5 ± 2 months).

Table 2. Operative Data

	U-Clips	Prolene	*P*
Operative status (urgent & emergent)	42%	59%	.07
No. of vessels bypassed	2.9 ± 1.0	3.2 ± 1.2	.33
Cross-clamp time (proximal and distal), min	63 ± 25	54 ± 24	.028
Pump time, min	98 ± 27	81 ± 20	.001
No. of distal arterial anastomoses	1.6 ± 1.1	1.5 ± 0.9	.4
Off pump	27%	28%	.74
Sequential anastomoses	22%	12%	.058

Table 3. Postoperative Data*

	U-Clips	Prolene	*P*
Blood use, units	1.3 ± 1.5	1.2 ± 1.7	.82
Ventilation time, h	5.0 ± 1.6	5.3 ± 1.4	.73
Postoperative MI	0%	0%	>.99
Length of stay, d	5.5 ± 1.7	5.9 ± 2.1	.47
Expected mortality rate	3.2 ± 4.2	3.1% ± 4.8%	.6
Observed mortality rate	2%	1%	.53

*MI indicates myocardial infarction.

One patient died from cancer. The Canadian Cardiovascular Society functional class was either class I or class II in 90% of patients. No patient in either group required postoperative angiography for any clinical indication, or repeat revascularization procedures.

DISCUSSION

Prolene monofilament suture using a running technique has become the standard for a vascular anastomosis. Purse stringing is a possible complication, especially in small vessels (1-1.5 mm). The nonreactivity and smooth glide through the tissue coupled with excellent needle technology has enhanced the surgeon's ability to perform precise, leak-free anastomoses.

Alternative approaches including penetrating and nonpenetrating staples [Bowen 1996, Heijmen 1999], bioadhesives [Bowen 1996, Gundry 2000], and laser welding [Tulleken 1997, Phillips 1999] have had limited success and minimal clinical adoption. The technical challenge of minimal access approaches to the coronary vessels, especially with robotic techniques, presents challenges primarily with time-consuming knot tying. Devices for deploying connectors to fashion anastomoses are under intensive development but remain experimental. These devices force the tissue to conform to the device, and the designs may have limited adaptability because of vessel characteristics such as tortuosity, plaque at the anastomosis, and very thin vessel walls.

Therefore the Coalescent U-Clip has several advantages. From the surgeon's perspective the learning curve is minimal. Conventional judgement in suture placement is preserved. Each stitch has a new needle. Nitinol is a nickel and titanium alloy. Endothelium covers the luminal side of the clip with minimal tissue reaction [Hill 2001]. The technique of employing interrupted sutures placed circumferentially around the anastomosis produces an accurate, compliant, secure joining of the vascular tissues. The release mechanism of the U-Clip was reliable.

Table 4. Postoperative Complications

	U-Clips	Prolene	*P*
Stroke	0%	0%	>.99
Renal failure	2%	1%	.79
Reoperation for bleeding	2%	1%	.89
Tracheostomy	0%	1%	>.9
Atrial fibrillation	17%	22%	.38
Sternal infection	0%	3%	.31

The elimination of knot tying with an interrupted suture technique provides a superior anastomosis [Young 1978, Loop 1979, Loop 1986, Falk 2000, Tozzi 2001]. For minimal-access cases, the need for suture management and the assistant "following" the suture is eliminated. Adaptation to robotic procedure allows the U-Clip to be an "enabling technology" [Ohtsuka 1997].

The clinical experiences reported in this paper confirm that CABG patients undergoing surgery using the Coalescent U-Clip will do well. The small increase in cross-clamp time does not have an adverse clinical impact. The potential benefit of a technically superior anastomosis is a goal well worth the expense to use this technology. Clinical studies both in animals and humans have confirmed pathologically [Hill 2001] and angiographically [Caskey 2002] minimal reactivity and near 100% patency rates [Lytle 2000, Ono 2002].

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