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Application of a New Suture Material Called the U-Clip for Composite and Sequential Grafting with Off-Pump Coronary Bypass Surgery

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ABSTRACT

Background. The U-Clip was found to facilitate the interrupted anastomosis of coronary artery bypass grafts (CABG). This device may be beneficial especially in multivessel off-pump CABG (OPCAB) using composite grafts or sequential anastomosis. The aim of this study was to evaluate our early clinical experience using the U-Clip in OPCAB cases.

Methods. This retrospective study included 118 patients who underwent off-pump CABG between 2001 and 2004. The mean age of the 91 men and 27 women was 69.5 ± 8.0 years (range, 47-85). The U-Clip was adopted for sewing 73 proximal ends of the free graft to the side or end of the inflow conduit to prepare the composite graft. The U-Clip was also applied to 112 distal anastomoses, especially to the side-to-side anastomosis of the sequential graft.

Results. Hospital mortality rate was 0.8% (1/118). The early patency rate of distal anastomoses using the U-Clip was 95% (96/101). The early patency rate of proximal anastomoses using the U-Clip was 98.4% (62/63). Interim angiography was performed in 12 patients (range, 3.8-42 months; average, 16 months). In these 12 patients, a total of 8 proximal anastomoses of conduits using the U-Clip were all patent without stenosis. The patency rate of a total of 10 distal anastomoses in the 12 patients using the U-Clip was 100%.

Conclusions. The U-Clip–interrupted anastomosis enables a safe, definite, and rapid end-to-end or end-to-side connection of arterial grafts. We therefore consider the U-Clip to be a useful suture material especially for multivessel OPCAB using multiple arterial grafts.

INTRODUCTION

Off-pump coronary artery bypass grafting (OPCAB) has been widely performed as a strategy to avoid complications associated with cardiopulmonary bypass in the past few years. However, aortic manipulation can cause brain complications even in OPCAB. A solution for avoiding such complications is revascularization using only arterial conduits with an "aortic no-touch technique" in OPCAB. In the application of this method, the frequency of using a composite graft and sequential anastomotic technique has increased. As a result, the technical difficulties associated with anastomosis have also increased. Moreover, a high incidence of incomplete revascularization and graft occlusion has been reported in OPCAB surgery, which was secondary to the technical difficulty that required a long learning curve for the surgeon [Kahn 2004; Parolari 2005]. The meta-analysis and consensus statement from the 2004 ISMICS Consensus Conference stated that the number of grafts performed and the completeness of revascularization is slightly reduced with OPCAB in comparison to conventional CABG and the results likely depend on the surgeon's expertise [Puskas 2005].

The interrupted suture technique avoids the purse-string effects seen with continuous suture techniques, but it tends to require a long time for knot tying. The U-Clip (Medtronic, Minneapolis, MN, USA) is a self-closing nitinol surgical clip device that facilitates the performance of an interrupted anastomosis without knot tying, thereby producing a high-quality anastomosis [Hill 2001; Ono 2002].

We have performed interrupted suture techniques using the U-Clip in OPCAB surgery. The purpose of the present retrospective study was to review the early and midterm clinical efficacy of U-Clip anastomosis in OPCAB.

METHODS

From August 2001 to August 2004, 217 patients underwent OPCAB surgery. Among them, 118 patients received the U-Clip. Our indications for OPCAB included patients who were considered to be at high risk for on-pump CABG because of comorbidities such as cerebrovascular or carotid disease, renal failure, aortic atherosclerosis, and chronic obstructive lung disease. Contraindications for OPCAB included an extremely small coronary artery and hemodynamic instability. The U-Clip was adopted for sewing the proximal end of the free graft to the side or end of the inflow conduit to construct the composite graft. The U-Clip was

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Table 1. Patient Demographics*

No. of patients	118
Age, y (range)	70 (47–85)
Sex ratio, M:F	92:26
No. of diseased vessels	2.6 ± 0.6
LMT ≥75%	22 (2.2%)
NYHA class, preoperative	2.8 ± 0.6
History of MI	46 (39%)
LVEF, %	62 ± 13
Emergency	10 (8.5%)
Cerebrovascular disease	36 (31%)
Ascending aortic lesion	39 (33%)
Renal failure	20 (17%)
COPD	12 (11%)
Diabetes mellitus	67 (57%)
Hypertension	76 (64%)
Hyperlipidemia	52 (44%)

*Values are expressed as mean ± SD. LMT indicates left main trunk lesion; NYHA, New York Heart Association; MI, myocardial infarction; LVEF, left ventricular ejection fraction; COPD, chronic obstructive pulmonary disease.

also applied to distal anastomoses, especially to the side-to-side anastomosis of the sequential graft. The mean age of the 91 men and 27 women was 69.5 ± 8.0 years (range, 47-85). The preoperative states of all cases are shown in Table 1. We obtained arterial conduits (an internal thoracic artery [ITA], a radial artery, and a right gastroepiploic artery [RGEA]) as a skeltonized graft using an ultrasonic scalpel (Harmonic scalpel; Ethicon Endo-Sugery, Cincinnati, OH, USA). We operated on the patients by a median sternotomy and used deep pericardial sutures and a suction-type stabilizer. To avoid perioperative neurological complications, no side clamp was ever applied to the ascending aorta, and free grafts were used

Table 2. Operative Results*

No. of bypasses/patient	3.4 ± 0.9
No. of graft-graft anastomosis	79
Using U-Clip	73 (92%)
No. of distal anastomosis	396
Using U-Clip	112 (28.3%)
Postoperative complication	
IABP	6 (5.1%)
Stroke	1 (0.8%)
PMI	0 (0%)
Hospital death	1 (0.8%)
Early angiographic patency ratio	362 studied (93.6%)†
FitzGibbon grade A‡	333
FitzGibbon grade B‡	6
FitzGibbon grade O‡	23

*IABP indicates intra-aortic balloon pumping; PMI, perioperative myocardial infarction (new Q or peak CKMB >100 ng/mL).

†Patency with or without stenosis.

‡A indicates excellent; B, graft narrowing to less than 50% of grafted coronary artery; O, occlusion.

Table 3. Coronary Distal Anastomosis Using the U-Clip*

Type	Site		Grafts
Side-to-side			
Dx	55	RA	34 (38)†
LAD	6	ITA	47 (49)†
LCX	37	RGEA	4 (4)†
RCA	11	SVG	16 (18)†
Subtotal	109		101 (109)†
End-to-side			
LAD	2	LITA	2
LCX	1	RA	1
Subtotal	3		3
Total	112		104 (112)†

*Dx indicates diagonal branch; RA, radial artery; LAD, left anterior descending branch; ITA, internal thoracic artery; LCX, left circumflex branch; RGEA, right gastroepiploic artery; RCA, right coronary artery; SVG, saphenous vein graft; LITA, left internal thoracic artery.

†Data presented as number of grafts (number of distal anastomoses).

in a composite fashion ("I" shape or "Y" shape) using the ITA or RGEA as inflow grafts. The ITA was used in 117 patients (99%), the bilateral ITA in 37 patients (31%), the RGEA in 46 patients (39%), and the radial artery in 61 patients (52%).

Postoperative anticoagulation was performed using low-dose oral aspirin (100 mg/d). Postoperative coronary angiography was performed to evaluate early graft patency in 103 patients (87.3%), from whom informed consents were obtained approximately 2 weeks after surgery and before being discharged. Interim angiography was also performed in 12 patients (10%) at a mean follow-up period of 16 months (range, 3.8-42 months). The results for performing the interim angiography revealed the return of angina in 3 patients (25%), congestive heart failure in 1 patient (8%), and 8 asymptomatic patients (67%).

RESULTS

The U-Clip was used for 112 of 396 total distal anastomoses (28%), and 73 of 79 composite grafts (92%). Other anastomoses were performed using the running anastomotic technique with polypropylene monofilament suture. The average number of U-Clips used for 1 anastomosis was 8.0 ± 2.8 in distal end-to-side anastomosis, 4.9 ± 1.5 in proximal side-to-side anastomosis, and 9.4 ± 1.3 in proximal anastomosis of the conduit. The average time required to perform distal anastomosis using the U-Clip was 7.3 ± 2.1 minutes for an end-to-side fashion and 6.3 ± 2.2 minutes for a side-to-side fashion. The clinical outcome data are presented in Tables 2, 3, and 4. The hospital mortality rate was 0.8% (1/118). According to the classification of FitzGibbon [1996], the overall early patency rate (FitzGibbon grade A + B) was 93.6%. The early patency rate of distal anastomoses using the U-Clip was 95% ([FitzGibbon grade A, 96 + grade B, 0]/101) (Tables 3 and 4). The early patency rate of proximal anastomoses using the U-Clip was 98.4% (Tables 5 and 6). In the 12 patients who underwent an interim angiography at an average of 16 months (range, 3.8-42 months), the overall

Table 4. Coronary Anastomosis Using the U-Clip: Angiographic Patency*

Type	No. Studied	FitzGibbon Grade†			Early Patency Ratio (A + B)/(A + B + O)
		A	B	O	
Side-to-side					
LAD	5	5	0	0	100%
Dx	51	50	0	1	98.0%
LCX	32	29	0	3	90.6%
RCA	10	9	0	1	90.0%
Subtotal	98	93	0	5	94.9%
End-to-side	3	3	0	0	100%
Total	101	96	0	5	95.0%

*LAD indicates left anterior descending branch; Dx, diagonal branch; LCX, left circumflex branch; RCA, right coronary artery.

†A indicates excellent; B, graft narrowing to less than 50% of grafted coronary artery; O, occlusion.

patency rate of distal anastomoses was 86% (31/36). Eight proximal anastomoses of the conduits using the U-Clip (I shape, 3; Y shape, 5) were all patent without stenosis (Figures 1 and 2). The patency rate of 10 distal anastomoses using the U-Clip (side-to-side, 9; end-to-side, 1) was 100%.

DISCUSSION

There are 2 major advantages when performing an anastomosis using the U-Clip. First, the anastomosis using the U-Clip creates an interrupted suture, and anastomotic stricture by a purse-string effect that can possibly occur with a running suture technique is avoided. Second, an interrupted suture using the U-Clip has preserved anastomotic compliance; therefore the diameter of the interrupted anastomosis varies depending on the cardiac cycle or dilatation of the graft and the coronary artery. Using the U-Clip, we can perform an interrupted suture in a shorter time than is possible with the conventional suturing method.

There are numerous studies describing the superiority of a simple interrupted suture during coronary artery anastomosis [Loop 1979; Loop 1986; Gerdich 2002; Tozzi 2001; Wolf 2003]. The use of interrupted sutures for left ITA–left anterior descending branch anastomoses has shown excellent long-term patency rates [Loop 1979; Loop 1986]. A recent multicenter prospective 6-month angiographic evaluation of coronary artery graft interrupted anastomoses by use of the U-Clip also showed favorable results [Wolf 2003]. Gerdisch evaluated the contraction and dilation of the anastomosis by intravascular ultrasound in a bovine coronary artery bypass model [Gerdisch 2002]. The use of interrupted sutures using the U-Clip showed a high compliance of the anastomosis in comparison to continuous sutures using polypropylene thread. The anastomosis could dilate in line with the dilation of the coronary artery and graft and improve the bypass graft flow. Demaria showed that the U-Clip did not cause any endothelial cell functional disorder while preserving the compliance of the anastomosis in a coronary artery bypass model of a pig [Demaria 2003].

Table 5. Graft-to-Graft Anastomosis Using the U-Clip: Arrangements*

Type	Branches/Extension				
	RA	ITA	RGEA	SVG	Total
End-to-side					
LITA (n = 33)	26	4	2	1	33
RITA (n = 2)	1		1		2
RGEA (n = 6)	4			2	6
Subtotal					41
End-to-end					
LITA (n = 6)	5		1		6
RITA (n = 26)	20			5	25
		1			1
Subtotal					32
Total					73

*RA indicates radial artery; ITA, internal thoracic artery; RGEA, right gastroepiploic artery; SVG: saphenous vein graft; LITA, left internal thoracic artery; RITA, right internal thoracic artery.

Table 6. Graft-to-Graft Anastomosis Using the U-Clip: Angiographic Patency*

Type	No. Studied	FitzGibbon Grade*			Early Patency Ratio (A + B)/(A + B + O)
		A	B	O	
End-to-side	34/41	33	0	1	97.1%
End-to-end	29/32	29	0	0	100%
Total	63/73	62	0	1	98.4%

*A indicates excellent; B, anastomosis narrowing to less than 50% of branch/extension graft; O, occlusion.

The opportunity to use composite grafts for arterial grafts has increased recently in OPCAB surgeries. The anastomotic quality at the time of preparing the composite graft is an important factor that affects the flow capacity of the graft. In addition, an anastomotic stricture or relative stricture with dilation of graft can also be avoided by using the U-Clip, and optimum blood-flow maintenance can be expected.

The side-to-side anastomosis in a sequential bypass using the arterial graft is minimal and delicate, and the degree of technical difficulty is high. By using the U-Clip, we could perform a side-to-side anastomosis easily and in a short time. We can usually perform a side-to-side anastomosis using only 4 U-Clips within 5 minutes. As a result, we were able to obtain acceptable early operative results and an early patency rate. In our present study, the early graft patency ratio of the distal anastomosis using the U-Clip was 95%. This value is relatively low in comparison to previous nonrandomized studies showing excellent early graft patency [Calafiore 1999; Pukas 2001]. However, our findings are comparable with a recent randomized study in Japan [Kobayashi 2005]. The patency rate of the distal anastomosis by use of the U-Clip was relatively low in the circumflex and the right coronary artery territory in comparison to the left anterior descending artery in present our study (Table 4). We used an ITA graft for the left anterior descending artery area, and we selected the radial artery, gastroepiploic artery, and saphenous vein graft for the revascularization of the circumflex and the right coronary artery area. These differences in graft material and target coronary territory might have influenced the early patency rate. However, we believe that the application of the U-Clip did not cause a deterioration of the early patency rate.

The exact etiology of anastomotic stenosis and bypass graft failure is not known, but intimal hyperplasia, regarded as a response to early surgical trauma and late perianastomotic compliance mismatch, has been proposed as the primary cause of patency deterioration [Guidoin 1981; Ballyk 1998]. Intimal hyperplasia has also been thought to be the major cause of in-stent restenosis in coronary artery and peripheral artery stents [Lowe 2002]. The biocompatibility of stent material is important; because the U-Clip is made of nitinol, a shape-memory alloy widely used for endoluminal stents and anastomotic devices, it reduces thrombus deposition and the

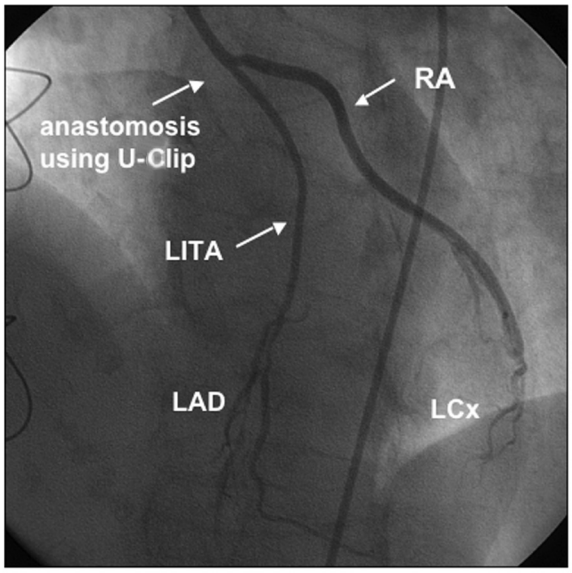

Figure 1. An angiogram 19 months after surgery demonstrating end-to-side anastomosis of the left internal thoracic artery (LITA) and a radial artery (RA) Y-graft using U-Clips.

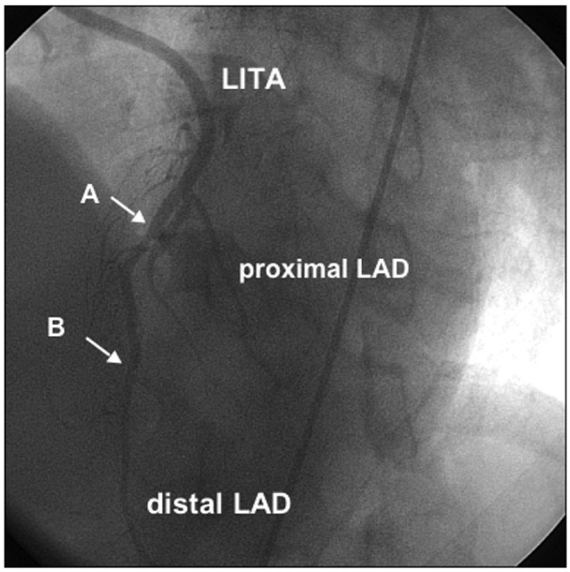

Figure 2. An angiogram 44 months after surgery showing the left internal thoracic artery (LITA) anastomosed to the mid (arrow A) and the distal portion (arrow B) of the left anterior descending artery (LAD) using U-Clips.

following inflammatory reaction [Tepe 2006]. Moreover, there is extremely little exposure of the suture materials to the intimal side of the anastomosis with the U-Clip compared with intracoronary stents. In addition, traumatic injury to the vascular wall by the U-Clip may be comparable to that of the conventional polypropylene sutures with a needle. Therefore, the occurrence of the intimal hyperplasia in the anastomosis using the U-Clip is expected to be almost the same as that of conventional suture material. In the bovine model of the right ITA–to–coronary artery anastomosis using the U-Clip, Hill and colleagues demonstrated a U-Clip that was bare in an anastomotic line could be covered by a smooth neointima 2 weeks postoperatively [Hill 2001]. However, the possibility of anastomotic stenosis resulting from long-term intimal hyperplasia still remains unclear. Caskey performed an angiographic evaluation at 6 months postoperative for 17 cases that used the U-Clip for a left ITA–left anterior descending branch anastomosis under OPCAB and confirmed good graft patency with no evidence of anastomotic stenosis in any cases [Caskey 2002]. In line with these results, the early postoperative result of the interrupted suture using the U-Clip was acceptable in our present study, which was limited to OPCAB cases with high comorbidity. We thus conclude that the U-Clip is a useful suture material for improving the early results of the OPCAB.

We did experience the dehiscence of a suture line due to excessive traction, and its strength thus seems to be inferior to that of conventional sutures using polypropylene. To improve this situation, we now use the U-Clip together with 1 or 2 polypropylene threads for fixing an anastomosis and have thus obtained good results.

We applied the U-Clip to few cases of end-to-side anastomosis, because hemorrhaging can easily occur when the anastomotic lines are not able to be put together properly. In addition, the overall cost rises because the number of U-Clips increases with this method.

The long-term results are still not clear, but the patency rate of anastomosis using the U-Clip was excellent, and the anastomotic configurations remained well and did not show any stenosis by intimal thickening due to a tissue reaction to the materials in our midterm angiographic examination. A follow-up study may be needed to evaluate the long-term patency in such cases.

In conclusion, the U-Clip–interrupted anastomosis produces a safe, definite, and rapid end-to-end or end-to-side connection of arterial grafts. We therefore regard the U-Clip to be a useful suture material, especially in a multivessel OPCAB using multiple arterial grafts.

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