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Quality of Anastomosis in Conventional On-Pump Coronary Artery Bypass Graft Surgery: Influence of the Interrupted Technique Using U-Clips and Correlation with Intraoperative Graft Flow Patterns

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ABSTRACT

Background. The interrupted suture technique in creating graft–coronary artery anastomoses in coronary artery bypass graft (CABG) surgery is hypothesized to be superior to the standard continuous technique. However, because of the increased time and knot tying involved with the interrupted technique, the continuous suture became standard. In 2000, the U-clip (a self-closing metal clip) was introduced to help in creating an interrupted anastomosis, although data regarding its clinical use are still somewhat limited. Intraoperative transit-time flow measurement (TTFM) of blood flow through an anastomosis is frequently used to assess quality of anastomosis creation; mean flow and pulsatile index (PI) are analyzed. PI should typically be between 1 and 5; higher values are associated with errors of anastomosis creation. The current study analyzes the difference in TTFM between U-clips and standard suture in CABG surgery.

Methods. The study population consists of 30 prospectively enrolled patients undergoing first-time on-pump conventional CABG surgery at St. Anthony Medical Center who were randomized to have their anastomosis created with either U-clips or suture. TTFM were recorded for left internal mammary artery to left anterior descending artery (LIMA-LAD) anastomoses.

Results. Of the 30 subjects enrolled (10 women), 12 operations were done with U-clips and 18 with suture. Body mass index (BMI) in the 2 groups was similar. In terms of mean flow, there was no difference between the 2 groups (29.8 ± 18.4 mL/min for U-clips versus 26.6 ± 11.0 mL/min for suture, $P = .57$). In terms of PI, again no difference was found (3.1 ± 1.3 for U-clips versus 2.5 ± 0.8 for suture, $P = .12$).

Conclusions. The findings of this study suggest that U-clips are comparable to the standard suture for LIMA-LAD anastomoses in conventional on-pump CABG surgery in terms of intraoperative assessment of graft flow.

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INTRODUCTION

The use of the interrupted suture technique in creating graft–coronary artery anastomoses in coronary artery bypass graft (CABG) surgery is hypothesized to be superior to the standard continuous, or running, suture technique. It is postulated that the interrupted technique avoids the "purse-string" effect of the running suture, which may result in a focal area of constriction and turbulence, which can lead to thrombosis or intimal hyperplasia [Young 1978; Baumgartner 1996]. However, this technique takes more time to complete than the standard technique and involves roughly 10 separate stitches and ties around the circumference of the anastomosis, compared to only 1 tie with the continuous suture that threads itself around the circumference before being tied. Both the increased time and number of knot ties involved with the interrupted technique have resulted in the running technique becoming standard practice.

In August 2000, a new FDA-approved self-closing clip device, the U-clip (Medtronic, Minneapolis, MN, USA), was launched to aid in the ease of creating an interrupted anastomosis by eliminating knot tying and suture management. This device has been shown in animal studies to adequately construct an interrupted anastomosis [Hill 2001; Demaria 2003; Gerdisch 2003]. There is a limited number of early studies in humans that favor the use of U-clips [Ono 2002; D'Ancona 2003; Wolf 2003]. However, because of the relative novelty of U-clips, their use is not yet standard practice among cardiac surgeons, although the existing limited number of published studies and the draw of easily creating an interrupted anastomosis have led to its use in some institutions. Cardiothoracic surgeons at St. Anthony Medical Center in Rockford, Illinois, started using U-clips in a portion of their patients in 2001.

Transit-time flow measurement (TTFM) of blood flow through a coronary artery bypass graft is frequently used to assess graft patency or quality of anastomosis [Walpoth 1998; D'Ancona 2000; Shin 2001; Hu 2003; Schmitz 2003]. Intraoperative use of TTFM allows surgeons to quickly gauge the quality of the anastomosis and have a chance to repair any substandard constructions.

The current study analyzes the differences in artery graft flow patterns between U-clips and the standard continuous suture in patients undergoing first-time conventional on-pump CABG surgery at St. Anthony Medical Center. The

use of U-clips is hypothesized to be superior to the standard suture in terms of intraoperative TTFM.

MATERIALS AND METHODS

U-Clips

Coalescent Surgical developed the U-clip to aid in the ease of creating an interrupted anastomosis; this technology was later purchased by Medtronic in late 2004. The clip itself is made of nitinol, a metal with memory capability, meaning that although it is in a U-shape when taken out of the packaging, it bends itself back to its original closed loop shape after being deployed. It is 1 to 1.25 inches long and 0.003 inches in diameter, and it is composed of 7 different components [Levin 2001]. The U-clip is loaded onto a standard needle and is deployed using a standard needle driver and forceps. After being passed through the tissues, squeezing on the distal end of the clip deploys it into its original closed loop shape; this brings the tissues together in a way equivalent to that of a knot [Levin 2001]. Thus, the U-clip eliminates knot tying and can ease the creation of an interrupted anastomosis which requires many such knots around the circumference of the anastomosis.

TTFM

TTFM uses Doppler technology to assess blood flow through a graft and has been shown to be accurate and reproducible [Matre 1994; Dean 1996]. This technology has seen increased use in CABG surgery intraoperatively due to its ability to quickly gauge the quality of the anastomosis, allowing one to correct any technical errors diagnosed from the flow characteristics produced by the flowmeter and flowprobe. Several flow characteristics are assessed, including mean flow (mL/min) and pulsatility index (PI). PI is calculated as: (maximum flow–minimum flow)/mean flow. Low mean flow is generally regarded to reflect anastomotic errors, and high mean flow is generally regarded to reflect patency [Schmitz 2003]. However, to use only mean flow in assessing quality of anastomosis may be imprecise because it has been suggested that mean flow does not necessarily correlate with clinical outcome [Louagie 1994]. On the other hand, the PI has been reported to be a good measure of flow pattern and anastomotic quality [Hu 2003] and can be useful in determining the need for graft revision [D'Ancona 2000]. PI may be a more reliable measure of anastomotic quality than mean flow because mean flow is dependent on the quality of the coronary artery being revascularized [Hu 2003]. PI values reportedly should fall between 1 and 5 [Hu 2003], with technical error in anastomosis creation leading to a higher PI value (ie, lower PI values are more favorable).

In the current study, TTFM was assessed using a MediStim flowmeter (Medtronic). During surgery, the flow probe was placed within 5 cm upstream of the anastomosis site and graft flow was measured while the heart was not cross-clamped (ie, blood flow was not a result of the function of the cardiopulmonary bypass pump). Both mean flow and PI were recorded.

Study Population

In a preliminary nonrandomized study presented at the International Society for Minimally Invasive Cardiothoracic Surgery meeting in 2002, H. Karamanoukian presented a study comparing 10 consecutive minimally invasive direct coronary artery bypass grafting (MIDCAB) surgeries using U-clips with 20 consecutive MIDCAB surgeries using continuous suture. These surgeries were done off-pump (ie, done on a beating heart without using the cardiopulmonary bypass pump). In studying left internal mammary artery (LIMA) to left anterior descending artery (LAD) grafts, there was a significant difference in the mean blood flow through the U-clip grafts (36.3 ± 10.7 mL/min) versus the continuous suture grafts (26.7 ± 8.8 mL/min) (P = .014). These data were later published in 2003 as a work in progress report [D'Ancona 2003].

The current study population consists of an equivalent number of patients (n = 30) undergoing first-time conventional on-pump CABG surgery at St. Anthony Medical Center in a study approved by both the Institutional Review Board of the University of Illinois College of Medicine–Rockford and the review board of St. Anthony Medical Center. All subjects had the same primary surgeon to avoid any interoperator variability. Because of the surgeon's personal conclusion of equipoise regarding U-clips and standard suture, and because of the surgeon's equal comfort in using either method with extensive experience in using both in clinical practice, subjects were randomized to receive either U-clips or standard suture. Subjects were enrolled prospectively in a sequential fashion between July 2004 and February 2005 (Table 1), and all subjects gave informed consent to have their data analyzed for the study. Inclusion criteria were: the patient's informed consent agreement was located in the patient's medical record file, the patient was having first-time CABG surgery with no concomitant valvular procedures, the surgery was nonemergency, the patient had a LIMA-LAD graft as 1 of their anastomoses, the surgery was done using conventional open heart CABG on a stopped heart using the cardiopulmonary bypass pump, and the patient had their grafts created with either U-clips or standard suture with the correlating TTFM available.

Statistical Analysis

Continuous variables in patient demographic groups were compared using a 2-sided unpaired t test. Flow characteristics between U-clips and suture were compared using 1-way analysis of variance incorporating BMI as a covariate. A P value of <.05 was considered significant for all purposes. Data are reported as mean ± 1 standard deviation unless otherwise stated.

RESULTS

Demographics

The frequency of the different types of grafts is shown in Table 2. LIMA-LAD grafts and saphenous vein to obtuse marginal artery (SVG-OM) grafts were the only ones that occurred in sufficient quantity to analyze. All subjects had LIMA-LAD grafts (n = 30), with 12 receiving U-clips and 18 receiving standard sutures (Table 3). There was no difference in mean age between the 2 groups (P = .20). Furthermore, there was no difference in mean BMI between the 2 groups (P = .60). Thus, the groups are comparable.

TTFM of Suture versus U-Clips

In terms of artery grafts, LIMA-LAD analysis shows that the mean blood flow is equivalent in the 2 groups (P = .57) (Table 4).

Table 1. Chronological Order of U-Clip versus Suture Surgeries

Surgery #	Type of Graft
1	Suture
2	Suture
3	Suture
4	U-Clips
5	Suture
6	Suture
7	U-Clips
8	U-Clips
9	Suture
10	Suture
11	U-Clips
12	U-Clips
13	Suture
14	Suture
15	Suture
16	Suture
17	U-Clips
18	U-Clips
19	Suture
20	Suture
21	U-Clips
22	U-Clips
23	U-Clips
24	Suture
25	Suture
26	U-Clips
27	Suture
28	Suture
29	U-Clips
30	Suture

In comparing PI scores, U-clips were associated with higher PI scores, but the difference was not significant ($P = .12$).

DISCUSSION

Main Findings

Because no difference was found when comparing U-clips to standard suture for both mean flow and PI, the results of this study suggest that U-clips are comparable to the standard suture in terms of intraoperative graft flow. Furthermore, the mean flow and PI values for each group fall within the ranges considered to reflect acceptable graft quality.

Previous Studies

Several studies have looked at the use of U-clips in animal heart models. Hill et al [2001] studied the use of U-clips to create a right internal thoracic artery to coronary artery anastomosis in 13 consecutive calves. They found that at the time of harvest all 13 calves had patent anastomoses as measured by angiography (FitzGibbon grade A criteria). Three calves were harvested at day 7, 8, and at 8 weeks, and 2 at 26 weeks. Demaria et al [2003] compared the use of U-clips versus conventional continuous suture in a porcine heart model in terms of developing endothelial dysfunction after the anastomosis creation. They found that there were no statistically significant differences between the U-clip, conventional continuous suture, and control groups in terms of the endothelium-dependent relaxation response to bradykinin. Gerdisch et al [2003] compared the use of U-clips versus standard continuous suture in the acute bovine heart model in terms of blood flow and vessel wall function. They found that the use of U-clips resulted in superior geometric consistency and greater physiologic compliance as well as fewer disturbances to the flow waveform compared to the standard continuous suture.

A few studies have analyzed the clinical use of U-clips in the patient population. In 2003, Shemin et al, analyzing 59 patients, found that U-clips were similar to conventional suture in terms of operative mortality, postoperative myocardial infarction, stroke, renal failure, and blood transfusion. Ono et al [2002] studied 14 first-time CABG patients who had their LIMA-LAD grafts done with U-clips and found that, of the 12 patients who had angiography performed at 6 months, all of the anastomoses were patent. In a study published in 2003, Wolf et al studied 82 patients who had their LIMA-LAD grafts done with U-clips and found that, of the 63 patients who had angiography done at 6 months, all the anastomoses were patent.

Table 2. Distribution of Graft Types*

Graft	Count
OM-ramus	1
Diagonal-diagonal	1
Intermediate	1
LIMA-LAD	30
LIMA-ramus	1
SVG-acute marginal	1
SVG-circumflex	2
SVG-diagonal	10
SVG-distal circumflex	2
SVG-LAD	2
SVG-OM	17
SVG-PDA	7
SVG-ramus	5
SVG-RCA	8
SVG-other	3
Total	91

*OM indicates obtuse marginal artery; LIMA, left internal mammary artery; LAD, left anterior descending artery; SVG, saphenous vein graft; PDA, posterior descending artery; RCA, right coronary artery.

Table 3. Demographics of Patients for Both LIMA-LAD Anastomosis*

Patient Data LIMA-LAD	U-Clips	Suture
Patients, n (women, n)	12 (3)	18 (7)
Mean age, y	70.4 ± 8.1	65.3 ± 11.8
Mean BMI	29.9 ± 6.3	28.7 ± 6.1

*Data are expressed as mean ± 1 standard deviation. LIMA indicates left internal mammary artery; LAD, left anterior descending artery; BMI, body mass index.

Table 4. Transit-Time Flow Measurement of Suture versus U-Clips*

LIMA-LAD	U-Clips	Suture	*P*
Mean flow, mL/min	29.8 ± 18.4	26.6 ± 11.0	.57
PI	3.1 ± 1.3	2.5 ± 0.8	.12

*Data are expressed as mean ± 1 standard deviation. LIMA indicates left internal mammary artery; LAD, left anterior descending artery; PI, pulsatility index.

As discussed earlier, D'Ancona/Karamanoukian compared U-clips to standard continuous suture in creating the LIMA-LAD grafts in patients and used TTFM to analyze the flow patterns intraoperatively [D'Ancona 2003]. Twenty consecutive subjects received continuous suture and the next 10 received U-clips. They found that mean blood flow significantly differed between the 2 groups. Furthermore, they reported that PI was significantly different as well (3.1 ± 0.9 for continuous suture versus 1.8 ± 0.3 for U-clips, $P = .0001$). These results are in contrast to what is found in the current study, where there is no difference between standard suture and U-clips in terms of mean flow or PI.

It is unclear what is causing the discrepancy between the findings reported by D'Ancona/Karamanoukian and those reported in the current study. The difference may lie in the type of surgery performed. In the Karamanoukian study, a MIDCAB was performed in all patients, where surgery was done without a full sternotomy and was done on a beating heart (ie, without stopping the heart and without using a cardiopulmonary bypass pump). In the current study, a conventional open heart CABG surgery was done in all patients (ie, surgery was performed with a full sternotomy and performed on a stopped heart using a cardiopulmonary bypass pump). The difference may also lie in study design; whereas in the current study, those receiving U-clips were mixed in with those receiving standard suture in terms of enrollment, in the Karamanoukian study all those receiving standard suture were sequentially enrolled together and those receiving U-clips were likewise sequentially enrolled afterwards. Finally, the difference may lie in that different surgeons were involved in the 2 different studies.

Implications

The findings of this study suggest that U-clips are comparable to the standard suture in conventional on-pump CABG surgery in terms of intraoperative assessment of graft flow. In addition, the graft flow values fall within values considered acceptable for good anastomotic quality.

Limitations

There are several limitations to the present study. First, the study enrolled only 30 subjects; however, in a previous study of MIDCAB off-pump patients, a difference was found using only 30 subjects. Second, angiography was not done in this population (eg, at 6 months). This was not feasible because of limited funding. However, the findings of the current study may still have implications in terms of immediate assessment of graft patency using TTFM and in assessing the need for graft revision intraoperatively.

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