

# Surgical Coronary Revascularization Using an Off-Pump, No-Touch Technique: The Cyclone (Hexalon) Experience

# Jeffrey M. Schussler<sup>1,2</sup>, Theodore T. Theologes<sup>3</sup>, Baron L. Hamman<sup>3\*</sup>

<sup>1</sup>Division of Cardiology, Baylor University Medical Center, Dallas, TX, USA <sup>2</sup>Texas A & M College of Medicine, Dallas, TX, USA <sup>3</sup>Division of Cardiothoracic Surgery, Baylor University Medical Center, Dallas, TX, USA Email: <u>Baron.Hamman@Baylorhealth.edu</u>

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#### Abstract

The Cyclone<sup>™</sup> System (Castlewood Surgical, Inc., Concord, MA) is a novel device that facilitates the attachment of the saphenous vein onto the ascending aorta for the purpose of creating a bypass graft during a coronary artery bypass grafting (CABG) operation. It allows the surgeon to perform a hand-sewn anastomosis with no disruption of the intima of the aorta, and no need for partial clamping. During a 36-month period 109 CABG operations were performed, and the Cyclone<sup>™</sup> System (and its predecessor, the Hexalon<sup>™</sup>) was utilized to create 138 proximal anastomoses. This study demonstrates that this is a safe and effective method of creating a clampless, no-touch proximal anastomoses during off-pump CABG.

# Keywords

No Touch, Clampless, Coronary Bypass, CABG, Anastomoses, Stroke

# **1. Introduction**

Several devices have been introduced to the market over the past 10 years in an effort to avoid the use of a clamp during coronary artery bypass grafting—these devices allow the surgeon to create an aortic anastomosis without manipulation or cross-clamping the aorta. In April, 2009, a new device was introduced to the market, the Hexalon<sup>TM</sup> System. Initial evaluation of this device was promising, but only limited in scope [1]. This paper reports on our larger clinical experience using this device, and its subsequent iteration, the Cyclone<sup>TM</sup> System.

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<sup>\*</sup>Corresponding author.

#### 2. Patients and Methods

Between April 2009 and March 2012, a single surgeon (BLH) at Baylor University Medical Center performed 138 proximal anastomoses on 109 patients using a new device which facilitated clampless, no-touch aorto-conduit anastomoses. Device use was at the discretion of the operator in order to avoid the use of a clamp during coronary artery bypass grafting. Surgery was performed off-pump in 105 out of 109 cases-four patients were converted to on-pump, but the anastomoses were performed using the device. The greater saphenous vein was used as the conduit for all of the anastomoses with the device. Patient characteristics are listed in **Table 1**. Rationale for surgery was typically angina pectoris, or symptoms which were considered an angina equivalent, cardiomyopathy felt to be ischemic in origin.

### 3. Device and Procedure Description

Early cases (53/109) were performed with the Hexalon<sup>TM</sup> System and later cases were performed with the Cyclone<sup>TM</sup> System. These devices are very similar in design with respect to the method that the vein graft is held in place, occluding the aortotomy during beating-heart surgery. The Cyclone<sup>TM</sup> is a newer version of the Hexalon and very similar in function, but has a smaller profile.

The Cyclone<sup>TM</sup> System fits onto the end of several off-pump stabilizers, such as the Maquet Acrobat-i<sup>®</sup> Stabilizer System, Medtronic Octopus<sup>®</sup> Evolution Tissue Stabilizer, Estech OPVAC Synergy<sup>®</sup> II and others. This allows the placement of the device on the aorta without the aid of a human assistant (Figure 1).

To use the device, the proximal end of the greater saphenous vein is prepared by transecting, spatulation or beveling. The vein is then placed between the six legs of the Cyclone<sup>TM</sup>. The vein is pierced by each of the six legs, taking a 2 - 3 mm bite of tissue. At this time, the surgeon examines the vein and ensures equidistance between each of the six legs; the legs are then closed together. A HeliGuard<sup>TM</sup> coil is then employed which encases the six legs of the Cyclone<sup>TM</sup>, such that the legs cannot get caught on the aorta when transferring it to the aortotomy (Figure 2).

The surgeon creates an aortotomy using the device of his choice. The aortotomy is covered digitally and the surgeon moves the Cyclone<sup>TM</sup> so that it is directly beside his finger and the aortotomy. In one motion, the surgeon removes his finger and places the loaded Cyclone<sup>TM</sup> inside the aortotomy. The HeliGuard<sup>TM</sup> is then removed by pulling straight back away from the aortotomy, facilitating unraveling of the coil mechanism. The legs of the Cyclone<sup>TM</sup> are opened fully using the iris mechanism, which typically achieves hemostasis. The vein is then sutured onto the aorta using the surgeon's technique of choice (e.g. running stitch, interrupted, etc.). The suture

Characteristic	Number (SD)	%
Age (Years)	$66.28 \pm 10.48$	
Male Sex	88	80.73
Hypertension	104	95.41
Diabetes	44	40.37
Previous Stroke	13	11.93
Peripheral Vascular Disease	22	20.18
Chronic Renal Failure (on Hemodialysis)	1	0.92
Renal Insufficiency (Cr > 1.9, Not on Hemodialysis)	6	5.50
Previous Myocardial Infarction	56	51.40
Low Ejection Fraction (≤40%)	37	33.94
Congestive Heart Failure (NYHA Class III or IV)	23	21.10
Urgent or Emergent Operation	50	45.87
Previous CABG	12	11.01

Table 1. Preoperative patient characteristics.



**Figure 1.** Cyclone<sup>TM</sup> device (A) attached to stabilizer arm. The veing graft is inserted through the tines (B) and the tips of the tines are placed into the end of the graft (C). The tines are then closed (D) and a HeliGuard<sup>TM</sup> is then placed on the ends of the tines (E) to protect them as they're inserted into the aortotomy. Once the graft is placed in the aortotomy the tines are opened to occlude flow out of the aortotomy (F) and the surgeon can sew in between the tines to complete the anastomosis.



**Figure 2.** Cardiac computed tomography angiogram, three-dimensional views comparing Symmetry (St. Jude Medical, Inc, St. Paul, MN) (A), Spyder and U-clip (Medtronic, Inc., Minneapolis, MN) (B), and Hexalon (Castlewood Surgical, Inc., Concorde, MA) (C)—facilitated anastomoses (arrows). Note the absence of any additional visible material at the ostium of the saphenous vein graft created using the Hexalon system (image reproduced with permission, Ann Thoracic Surgery) [1].

used in this series of patients was a suture on a half-circle needle (6 - 0 Prolene<sup>®</sup> polypropylene suture with a RB-2 needle, Ethicon, Somerville, NJ). This half-circle needle seems to make it easier to sew around the legs of the Cyclone<sup>TM</sup>. Once suturing is complete, the surgeon removes the Cyclone<sup>TM</sup> by pulling it at a 90° angle away

from the aorta. The device can then be rinsed in saline and used for subsequent proximal anastomoses for that patient.

#### 4. Results

Patient data was entered into the Society of Thoracic Surgeon's (STS) risk calculator in an effort to calculate the risk of mortality and other morbidities, such as stroke, dialysis and reoperation for bleeding. The risk calculator incorporates the risk models within the STS that are designed to serve as statistical tools to account for the impact of patient risk factors on operative mortality and morbidity [2].

In the study group, over 80% of patients were male, over 40% had type 2 diabetes mellitus and more than a third presented with an ejection fraction of less than or equal to 40% (**Table 1**). During the study period, proximal anastomoses were completed using the Cyclone<sup>TM</sup> System in 99.1% of the cases performed (n = 109). Two proximal anastomoses were not completed with the Cyclone<sup>TM</sup> System, and required the use of a partial occlusion clamp. All grafts (n = 227) were patent upon completion of the anastomosis as evaluated by flow measurement and Doppler flow analysis.

Clinical events are listed in **Table 2**. "Expected" results are based on STS data. There were two deaths: one patient initially presented to the hospital with severely decompensated congestive heart failure and acute renal insufficiency. The patient was operated on emergently, but did not recover following the operation. The other patient expired on post-operative day #45 of an uncontrolled gastrointestinal bleed. Neither death was felt related to the use of the device.

There was one cerebrovascular event which occurred in the perioperative period. This patient's stroke occurred on postoperative day three and was felt related to atrial fibrillation and not device-related.

#### 5. Discussion

Stroke is one of the most devastating complications following coronary artery bypass grafting (CABG) surgery. The recently published SYNTAX trial showed that the risk of stroke following CABG is 3.7% [3]. There have been several studies that have closely associated this complication with the location and extent of atherosclerotic disease of the ascending aorta [4]-[6].

In many cases, the presence of disease in the aorta dictates that the approach to the operation is altered. One way in which the surgeon can perform a CABG with little to no manipulation of the aorta is to perform the procedure *without the use of a clamp*. Recent studies have compared off-pump with on-pump coronary bypass, and have not found either technique superior in the reduction of peri-operative stroke. However, these off-pump surgeries are not necessarily "no-touch", whereby the aortic is not manipulated or partially clamped [7].

Clamping the ascending aorta, either with a crossclamp or with a partial occlusion clamp, can lead to an increase in cerebral emboli and perioperative stroke [5] [8] [9]. This is due to a disruption of atherosclerotic plaque on the intima of the ascending aorta [10] [11]. There is an increase in transcranial Doppler signals correlating with adverse neurological outcomes following coronary artery bypass grafting (CABG) operation using traditional cardiopulmonary bypass pump [10]. The extent of neurological injury is directly related to the number of emboli measured during the operation [10] [11].

A hand-sewn anastomosis with suture is the tried-and-true method that surgeons trust most when it comes to creating proximal anastomoses. Surgeons can create these anastomoses quickly, but during beating-heart surgeries, the problem of creating an anastomosis with a bloodless field remains a problem. Aortic-conduit anastomotic devices are available, which facilitate rapid creation of anastomoses, but come at a higher price than de-

Table 2. Postoperative complications.			
Complication	Expected (%)	Observed (%)	
Perioperative Death	2.46	2 (1.83)	
Stroke < 48 hours	1.48	0 (0.00)	
Stroke > 48 hours	1.48	1 (0.92)	
New-Onset Hemodialysis	5.38	1 (0.92)	
Reoperation for Bleeding	5.63	4 (3.67)	

Table 2. Postoperative complications.

sirable rate of occlusion [12]. The Cyclone<sup>TM</sup> device allows the surgeon to create a suture-based anastomosis without the use of a cross-clamp or a partial occlusion clamp, and without resorting to anastomotic devices. The Cyclone<sup>TM</sup> System allows the surgeon to provide an anastomosis in such a way that the intima of the aorta is not disturbed and the vein is not damaged while sewing it to the aorta.

There are limitations to this device. Due to its design, it is imperative that the anesthesiologist is able to maintain the systemic blood pressure within a tight window. Systolic pressure of 80 - 90 mmHg is considered optimal during creation of the proximal anastomosis. The Cyclone<sup>TM</sup> System requires that the pressure inside the aorta does not overcome the seal between the vein and the aortotomy. If the pressure is higher than 120 mmHg systolic, many times the seal between the legs of the Cyclone<sup>TM</sup> cannot withstand the pressure and a leak at that area development.

There are limitations to this study. This is a single hospital, single surgeon study. The patients were not randomized and no other method was used as a comparison.

The data regarding off-pump CABG (OPCAB) versus on-pump CABG remain conflicted. The OPCAB procedure gained favor initially as a method that would reduce the risk of cerebrovascular events and renal failure. Many of the larger studies are inconclusive and inconsistent. Recently, a few studies have favored OPCAB. In patients undergoing OPCAB, a *no-touch technique* was associated with significantly less strokes, 0.7% versus 2.3% (CI 95%, p = 0.004) [13]. In patients undergoing OPCAB, if total arterial revascularization was employed (no grafts off of the aorta), the stroke rate was zero percent; the control group of on-pump CAB patients' rate of stroke was 2.3% [14]. A third study compared three groups: on-pump, off-pump, and off-pump with no aortic manipulation (no grafts off of the aorta). The authors demonstrated that the on-pump group had a stroke rate of 0.9%, the off-pump group's stroke rate was 0.5% and the off-pump group with no aortic manipulation had a stroke rate of 0.1% [15].

More studies need to be conducted with respect to this device, preferably in a multi-center, multi-surgeon trial where the results can be compared with on-pump CABG and off-pump CABG where a partial occlusion clamp is used.

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