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Xpose™: A New Device that Provides Reproducible and Easy Access for Multivessel Beating Heart Bypass Grafting

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ABSTRACT

Background: Off-pump coronary artery bypass (OPCAB) is gaining acceptance and is now more widely used for coronary revascularization. Accessing the vessels, particularly on the lateral and inferior walls of the heart, can sometimes be challenging while the heart is beating.

Case Reports: The *Xpose*™ Access Device (*Xpose*™; Guidant Corporation, Cupertino, Ca.) was used in 5 patients undergoing beating heart surgery to position the heart for coronary grafting. Hemodynamic and mixed venous oxygen saturation (MVO_2) monitoring was performed with the device in place. In all cases, *Xpose*™ was successfully used to easily access and graft all of the target vessels including lateral and inferior wall vessels with the patients maintaining stable hemodynamic performance.

Conclusion: *Xpose*™ was used to successfully perform multivessel coronary bypass on all walls of the beating heart. These case reports suggest that use of the *Xpose*™ will facilitate and expand the ability to easily and consistently perform coronary artery bypass grafting on the beating heart.

INTRODUCTION

Enthusiasm for beating heart surgery was generated by the minimally invasive direct coronary artery bypass (MIDCAB) procedure as described by Dr. Frederico Benetti [Benetti 1985 and 1991] and expanded and validated by Dr. Antonio Caliafore's left anterior small thoracotomy (LAST) procedure [Caliafore 1996]. Off-pump multivessel grafting grew from this "new revolution" as instrumentation was researched and developed by industries and improved from Dr. Michael Mack's original "fork stabilizer" [Mack, personal communicaton, 1996] to present day multivessel stabilizers. These stabilizers and beating heart instrumentation are continually upgraded and improved to allow surgeons to perform OPCABs with the same ease and consistency as they do arrested-heart bypasses. Surgeons' confidence, anesthesiologists' skill and acceptable outcomes [Caliafore 1998, Puskas 1998 and 1999, Spooner 1998, Hart 1999, Mack 1999] have been the other important factors in off-pump multivessel bypass growth.

One of the main areas of difficulty in multivessel grafting has been safe, reproducible, and easy access to the lateral and inferior wall vessels while maintaining the patient in an acceptable hemodynamic condition. Through a sternotomy the left anterior descending artery (LAD) is fairly easy to position for grafting. Surgeons are using many innovative ways to reach the lateral and inferior wall vessels, such as deep pericardial sutures [Lima 1995 and 1999] and sutures with slings. Another approach is by opening the right pleura widely to allow the heart to herniate into the right chest to roll the obtuse marginal (OM) vessels into view [Hart 2000]. These maneuvers can cause extreme hypotension particularly during the "moment of death" placement of the deep pericardial sutures which can cause patients with severely impaired left ventricles or very tight proximal stenoses to decompensate and, thus, necessitating cardiopulmonary bypass (CPB). Sometimes it also requires a great deal of manipulation to position the heart for access to these vessels, still with suboptimal visualization.

CASE REPORTS

Xpose™ was used in 5 patients undergoing OPCAB. All patients had a minimum of 3 grafts performed with at least

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Table 1. Preoperative Demographics

	Sex	Age	EF	LVH	Procedure
1	F	74	45	Mild	LIMA-LAD, SVG-OM, SVG-PDB
2	F	56	50	None	LIMA-LAD, Radial-Ramus, SVG-PDB
3	M	50	40	Severe	LIMA-LAD, Radial-Ramus, SVG-PDB-LVB
4	M	65	15	Severe	LIMA-LAD, SVG-Ramus, SVG-PDB-LVB
5	F	47	50	None	LIMA-LAD, Radial-OMs, SVG-PDB-LVB

EF, ejection fraction (%); LVH, left ventricular hypertrophy; F, female; LIMA, left internal mammary artery; LAD, left anterior descending artery; SVG, saphenous vein graft; OM, obtuse marginal; PDB, posterior descending branch; M, male; LVB, left ventricular branch.

Table 2. Hemodynamics of Patient No. 1

	Pregraft	LAD	OM	PDB	Postgraft
Heart rate (beats/min)	56	76	67	62	72
Blood pressure (mm Hg)	136/61	114/72	137/68	142/80	140/70
Cardiac index	1.5	1.9	2.0	2.2	3.1
MVO_2	83	72	76	78	80
Inotropes (µg/min)	None	None	None	None	None

MVO_2, mixed venous oxygen saturation (%); LAD, left anterior descending artery; OM, obtuse marginal; PDB, posterior descending branch.

Table 3. Hemodynamics of Patient No. 2

	Pregraft	LAD	Ramus	PDB	Postgraft
Heart rate (beats/min)	70	72	76	76	84
Blood pressure (mm Hg)	113/60	128/64	112/63	123/70	110/60
Cardiac index	2.9	3.2	2.6	2.2	2.5
MVO_2	83	90	86	88	82
Inotropes* (µg/min)	Dopamine (5) NTG (20)	Dopamine (5) NTG (20)	Dopamine (5) NTG (20)	Dopamine (5) NTG (20)	Dopamine (5) NTG (20)

LAD, left anterior descending artery; OM, obtuse marginal; PDB, posterior descending branch; MVO_2, mixed venous oxygen saturation (%); NTG, nitroglycerine.
*Dopamine was started after induction for low heart rate and blood pressure and continued through the case.

1 vessel in the circumflex distribution. There were 3 women and 2 men. Ejection fractions ranged from 15% to 50% and left ventricular hypertrophy ranged from mild to severe (Table 1,). One patient (no. 5) had long-standing asthma and had been on steroids for several years. Hemodynamics and inotrope use for each patient are shown in Tables 2–6 (). Exposures for grafts of different vessels are shown in Figures 1–7 (): LAD, Figure 1 (); left ventricular branch (LVB) and posterior descending branches (PDBs) of the right coronary artery, Figures 2 and 3 (); obtuse marginal, Figures 4–6 (); and Ramus, Figure 7 (). Total time of

Table 4. Hemodynamics of Patient No. 3

	Pregraft	LAD	Ramus	LVB	PDB	Postgraft
Heart rate (beats/min)	60	64	60	57	61	65
Blood pressure (mm Hg)	110/62	131/75	116/67	113/68	100/60	120/60
Cardiac index	*	*	3.0	2.5	2.7	4.0
MVO_2**						
Inotropes (µg/min)	Epi (4)	Epi (4) Neo (40) NTG (20)	Epi (3) NTG (20)	Epi (3) NTG (20) NTG (25)	Epi (3) Neo (40)	NTG (25)

LAD, left anterior descending artery; LVB, left ventricular branch; PDB, posterior descending branch; MVO_2, mixed venous oxygen saturation (%); Epi, epinephrine; NTG, nitroglycerine; Neo, neosynephrine.
*No cardiac index was performed.
** Oximetrix Swann Ganz catheter was not used and MVO_2 readings not obtained.

Table 5. Hemodynamics of Patient No. 4

	Pregraft	LAD	Ramus	LVB	PDB	Postgraft
Heart rate (beats/min)	78	82	76	89	88	88
Blood pressure (mm Hg)	141/72	129/72	127/77	128/75	124/75	126/70
Cardiac index	2.2	2.0	1.7	1.2	1.6	2.4
MVO_2	83	78	77	59	68	78
Inotropes (µg/min)	None	None	None	Epi (2)	Epi (2)	

LAD, left anterior descending artery; LVB, left ventricular branch; PDB, posterior descending branch; MVO_2, mixed venous oxygen saturation (%); Epi, epinephrine.

Table 6. Hemodynamics of Patient No. 5

	Pregraft	LAD	OM	LVB	PDB	Postgraft
Heart rate (beats/min)	112	101	108	98	105	108
Blood pressure (mm Hg)	123/76	124/79	118/83	115/78	109/72	105/61
Cardiac index	1.7	3.3	3.0	3.1	2.7	3.4
MVO_2	86	91	87	84	86	88
Inotropes (µg/min)	None	None	None	None	None	None

LAD, left anterior descending artery; OM, obtuse marginal; LVB, left ventricular branch; PDB, posterior descending branch; MVO_2, mixed venous oxygen saturation (%).

Xpose™ application ranged from 38 to 85 minutes (Table 7,). The vacuum pressure used decreased from 300 to 225 mm Hg with a corresponding decrease in degree of hematoma (Figure 8,).

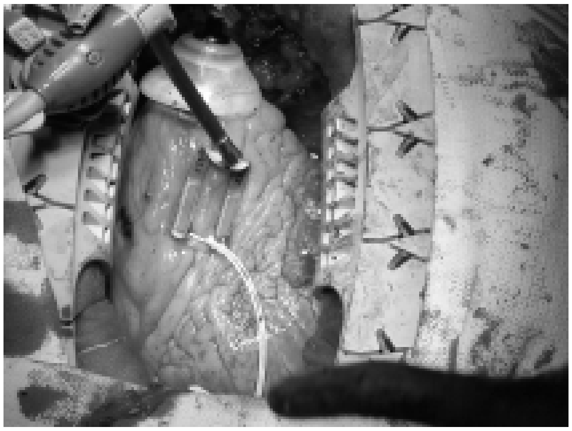

Figure 1. *Xpose*™ HSF LAD.

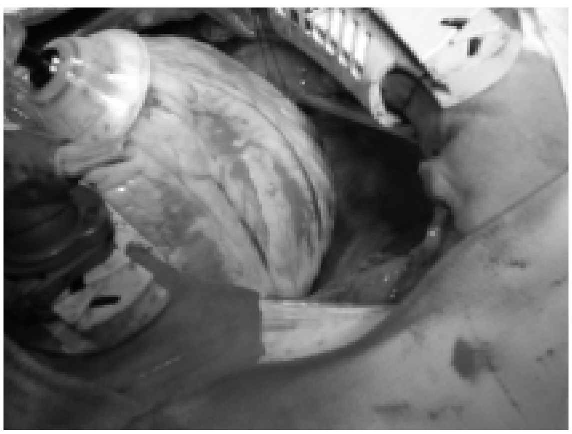

Figure 2. PDB and LVB.

Figure 3. LVB and PDB.

Figure 4. *Xpose*™ OM.

Figure 5. OM exposure.

Figure 6. *Xpose*™ OM.

The *Xpose*™ consists of a curved articulating arm with a bell shaped cup attached at the end by a swivel joint (see Figure 9,). The arm is attached to the stabilizer retractor with the quick release lock and can be placed at any point on the retractor to allow positioning of the heart. The cup is positioned on the apex of the heart then suction is applied through the cup to allow capture of the heart . The suction apparatus is any standard suction set up available in the OR . The arm can be disengaged from the stabilizer and repositioned without releasing the attachment to the

Figure 7. *Ramus.*

Figure 8. Haematoma.

heart. It is not necessary to place the deep pericardial sutrures to help with cardiac positioning. At the completion of the distal anastamoses, the suction is released and the heart returned to the pericardial well.The mount housing is made of reinforced polycarbonate, the shaft is aluminium and the cup is silione with polyurethane foam.

DISCUSSION

Successful myocardial revascularization on the beating heart should be performed without adverse effects on the patients. Access to the coronary vessels, particularly of the lateral wall has been challenging and has limited multivessel off-pump surgery. Surgeons are continually trying to find ways to easily, consistently, and safely access all coronary vessels for grafting with minimal hemodynamic compromise particularly in patients with impaired ventricles and all degrees of coronary stenoses [Grundeman 1998 and 1999, Douville 1999]. Deep pericardial sutures, patient positioning, slings, pharmacologic manipulation, and pleural invasion have all been used to achieve this goal. *Xpose*™ was used in these 5 patients to successfully position the heart to graft all of the target vessels. The device was easy to apply and to use to manipulate the heart without periods of extreme hypotension required by suture placement. Even though 1 patient with an impaired and severely hypertrophied left ventricle experienced hemodynamic changes with positioning, the lateral and inferior wall vessels were easily accessed and grafted with minimal pharmacologic support. The level of vacuum needed to maintain capture of the ventricle was varied with 225 – 250 mm Hg being the lowest for consistent apposition. The degree of hematoma caused by these pressures was less at the lower levels and, in all patients, epicardial hematoma had significantly resolved at the time of closing. As we gain more experience with the use of *Xpose*™, our potential to gently manipulate and position the heart to allow access to the vessels can expand our ability to safely revascularize these more difficult patients without use of the heart-lung machine.

Table 7. *Xpose*™ Access Device Time and Degree of Hematoma

Patient	Total Time of Application (min)	Degree of Hematoma	Vacuum Pressure Applied (mm Hg)
1	38	Severe	300
2	73	Moderate	275
3	85	Moderate	250
4	58	Mild	250
5	80	Mild	225

CONCLUSION

Performance of myocardial revascularization on the beating heart is a continually evolving process. *Xpose*™ was used to successfully perform multivessel coronary artery bypass on all walls of the beating heart. These case reports suggest that use of *Xpose*™ will facilitate and expand the ability to easily and consistently perform coronary artery bypass grafting on the beating heart.

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REVIEW AND COMMENTARY

1. Editorial Board Member MB134 writes:

a) This may be an incremental step forward in OPCAB-facilitating technology. Although this is an initial pilot study (or feasibility study), the authors do not state if there were patients in which the device was attempted and then abandoned. There is no control group. There is no comparison with another method at use in the same institutions.
b) There is no explanation of the device itself (how it works, its materials, its size, and its mechanism of action). I would not be in favor of accepting this paper unless the authors can describe the device in more detail and how it works.

The pull-away forces necessary to dislodge the device have already been studied, but are not specified in this paper. I would like to have the laboratory data on the pull-away forces in the paper

Authors' Response by Mercedes K.C. Dullum, MD:

a) This paper was submitted only as a case report of 5 cases and so there was no control group and no comparisons made to other groups. I agree that we would like to proceed with a randomized comparison trial of the device. It was used a couple of times by my partners but without data collection and I used it on 1 patient that we started to do off-bypass but converted to on-pump. This patient was a poor choice for off-pump and his conversion to on-pump was not related to the device. In our institution some surgeons use the 4 pericardial sutures and I use a single suture in the pericardium of the transverse sinus with vaginal packing for a sling.
b) The details of the device can also be published in a more detailed study including the laboratory data describing how it works. Application by suction (we found that 225 mm Hg was best) to the apex of the heart allows the heart to be gently manipulated and positioned.

2. Editorial Board Member LO23 writes:

This is an interesting new device. There are, however, a very limited number of patient applications on which to base a recommendation.

Did the authors, as they infer, use this device without opening the right pleura at all? Was the device used exclusively without the use of any other method during this evaluation period and, if not, why not?

Authors' Response by Mercedes K.C. Dullum, MD:

The right pleura was not opened to drop the heart over. The only other sutures are the ones that were placed on the cut edge of the left pericardium to keep the left lung from herniating in to the field. We did not have a need to use deep pericardial sutures or open the right pleura, so these maneuvers were not necessary.

3. Editorial Board Member KK138 writes:

a) This is an interesting approach for exposure during OPCAB surgery. The device is not described in sufficient detail, however. A more thorough description of the device would be helpful.
b) Also, placement and fixation of the device once the heart is in the desired position should be mentioned.
c) If the authors did hemodynamic measurements during application of the device these should be reported.
d) Can this device be used endoscopically? This question is of particular interest because endoscopic access to the CX and right coronary is really limited.

Authors' response by Mercedes K.C. Dullum, MD:

a) The cup portion of the device is applied to the apex of the heart then the arm is attached to the stabilizer retractor. *Xpose*™ can be attached to the retractor in many positions allowing greater flexibility for positioning.
b) The device is tightened on the retractor after the desired position is achieved.
c) Formal hemodynamic measurements were taken after the heart was in the position for grafting, not during application. (We felt that this would be the time of maximum compromise and would represent the worst possible hemodynamics)
d) It could be used endoscopically; however, at this time it would require a port large enough to pass the cup.

Invited Commentary from Paul Gründeman, MD, Utrecht University Medical Center, Heart Lung Institute, Utrecht, Netherlands

In the past five years, a number of elegant approaches have been developed in the laboratory and in the OR that provide the surgeon access to and exposure of the lateral and posterior wall in multi-vessel beating-heart surgery. Through sternotomy, the circumflex territory is most difficult to reach because the heart has to be moved out of the pericardial cradle with its apex pointing vertically. Subsequently, it remains fixed in an awkward extra-anatomic position for grafting. The maneuver is associated with a firm drop in arterial blood pressure that usually recovers incompletely over time, which is the result of an abruptly decreased stroke volume. Both the surgeon and anesthesiologist would feel more comfortable with a stable (compensated) hemodynamic condition of the patient allowing unhurried grafting on usually smaller vessels.

How does the proposed *Xpose*™ suction device fit in the existing strategies for cardiac displacement? As the authors mentioned, currently practiced measures of displacement may include the beating-heart flip by placing deep pericardial sutures (according to Lima), the use of supportive fabric tapes (according to Spooner and Calafiore), and a cut in the right lower corner of the pericardium combined with pleural invasion (according to Hart and Pym). Gravity proves to be a powerful tool in two ways: it grossly reverses the hemodynamic collapse by volume redistribution (Trendelenburg maneuver according to Gründeman) and improves exposure by right lateral decubitus body positioning (according to Gründeman). On examination, pharmacological manipulation is necessary.

All of the above mentioned techniques are being used depending upon surgeons' preference and are supplementary to each other. What they have in common is that the heart remains more or less untouched. All maneuvers, however, have the potential to influence cardiac function negatively. In the porcine model, we observed that biventricular function was impaired with vertical displacement owing to strangulation and to deformation of the heart chambers, which mostly affected diastolic function of the thin-walled right ventricle. Although all corrective measures have been taken, stroke volume and arterial pressure may not show full recovery despite highly enhanced preload pressures (Edgerton and Mack). In summary, there is no free ride for a displaced beating heart.

This feasibility study in five beating-heart CABG cases describes a technique that aims to facilitate the exposure of the target vessel by manipulating the apex with a suction device. By its simplicity and effectiveness, the device may prove to be a practical way to hoist the heart. Possibly, it helps to expand surgeons' ability to safely perform beating heart bypass surgery, specifically in the compromised hypertrophic left ventricle.

The authors are to be congratulated for their success in completing the operation without the need of conversion with acceptable hemodynamic conditions. The study must be expanded, however, by a prospectively randomized comparison to other retracting techniques that investigate safety, efficacy and necessity of the proposed method. The given hemodynamic data are to be completed with indices that include preload pressures in relation with stroke volume changes with the displacement maneuvers. In theory, diastolic function of the heart may have been improved by elongating the long axis of the left ventricle.

There are some concerns about the hematoma created by the device. At the end of 1995, we tested a similar approach in a pig model (Borst and Gründeman). An impressive apical hematoma and a kinetic area were observed after release of the suction cup. However, from experimental studies and clinical experience using the Octopus™ tissue stabilizer, we learned that small suction lesions (about 5 mm in diameter) are harmless and that epicardial suction produces negligible myocardial damage (according to Borst). Therefore, experimental animal data remains to be generated that provide detailed insight in the use of apical suction at various suction forces, i.e., the release of markers of myocardial injury, pathology of the injured tissue, including the presence of thromboembolic events in the coronary circulation, and patency of apical collaterals and regional myocardial function. It is unfortunate that this preliminary clinical report is not published together with experimental data that establish proof of concept and safety in an animal model.