

## Quantification of Mechanical Stabilization for the Performance of Off-Pump Coronary Artery Surgery

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### ABSTRACT

**Introduction:** Our objective was to analyze the motion of a coronary artery in 3-dimensional (3-D) space and to quantify the stabilization afforded by a mechanical arm using 3-D digital sonomicrometry.

**Methods:** The left anterior descending coronary artery (LAD) was exposed in swine ( $n = 7$ ) via sternotomy. A 2-mm sonomicrometry crystal was sutured to the LAD, and an acrylic (Plexiglas) ring with 3 2-mm crystals fixed in an equilateral triangle was placed in the oblique pericardial sinus. Sonomicrometry measurements were obtained before and 10 minutes after placement of a stabilizing arm. Traces were analyzed for motion and velocity on a beat-to-beat basis in the  $x$ ,  $y$ , and  $z$  planes by means of triangulation theory. Excursion was defined as the average maximum observed distance between LAD Cartesian positions  $p(k) = [px(k), py(k), pz(k)]$  over a beat such that the Excursion =  $\max(j, k \text{ in beat}) \sqrt{\{[px(j) - px(k)]^2 + [py(j) - py(k)]^2 + [pz(j) - pz(k)]^2\}}$ . The maximum and the average of the Cartesian velocity magnitude,  $v = \sqrt{vx(2)^2 + vy(2)^2 + vz(2)^2}$ , were also calculated.

**Results:** Analysis of the LAD motion in planar space demonstrated a biphasic pattern in all 3 planes that appeared to be stable through the duration of the data acquisition period. The stabilizer dampened the motion of the LAD to a monophasic pattern and reduced the total distance traveled by the LAD crystal in all 3 planes. Stabilization resulted in a significant reduction of excursion, the maximum Cartesian velocity, and the average Cartesian velocity of the LAD.

**Conclusions:** This method allows the precise quantification of LAD artery motion in 3-D space before and after the application of a stabilizing arm. We have demonstrated a significant reduction in the complexity of motion, the degree of motion in planar space, and the velocity of the LAD after application of a stabilizer.

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### INTRODUCTION

Off-pump coronary artery bypass (OPCAB) surgery allows the surgeon to perform anastomoses to distal coronary arteries without arresting the heart. Inherent to this type of procedure is the difficulty of operating on a "moving target" without compromising the accuracy of the anastomosis, long-term patency, or cardiac function. The advent of commercially available stabilizing devices has allowed surgeons to perform off-pump procedures with minimal morbidity and mortality and with patency rates similar to those of arrested heart surgery using cardiopulmonary bypass [Diegeler 1999, Omeroglu 2000, Amano 2001, Bowles 2001, Puskas 2001].

Multiple stabilizing devices are currently available to cardiac surgeons. These devices can be divided into two general classes, devices that stabilize the coronary arteries and surrounding epicardial tissue and use direct mechanical pressure and those devices that stabilize via application of a vacuum seal to the area surrounding the artery. Both types of devices have been used safely [Borst 1996, Jansen 1997a, Diegeler 1998, Holubkov 1998, Jansen 1998, Spooner 1999, Akpınar 2000]; however, there are no objective data evaluating the degree of stabilization afforded to the surgeon by either of these stabilizing devices. An earlier presentation of one of the first versions of the Octopus device (Medtronic, Minneapolis, MN, USA) reported 2-dimensional motion of an obtuse marginal branch artery measured with an epicardially placed beacon that was tracked with a standard video camera [Borst 1996]. The authors were able to show a reduction in the degree and complexity of the motion of the artery in a semi-quantitative manner.

An alternative approach to analyzing cardiac motion during its normal cycle is to use sonomicrometry crystals. These crystals, when coupled with the appropriate signal-processing software, allow the determination of distance traveled over time in 3-dimensional (3-D) space. Crystal pairs transmit and receive sound waves that travel through tissue. Distance is determined by assuming that tissue is predominantly water and using the fact that the velocity of sound through water is 1540 m/s. Current sonomicrometry technology allows spatial resolution to 0.0154 mm and a temporal resolution of up to 1000 Hz. This system allows a very detailed analysis of cardiac motion in both the stabilized and unstabilized condition and provides a means of determining total movement and velocity in 3-D space. Our objective in this study was to analyze the motion of the left anterior descending coronary

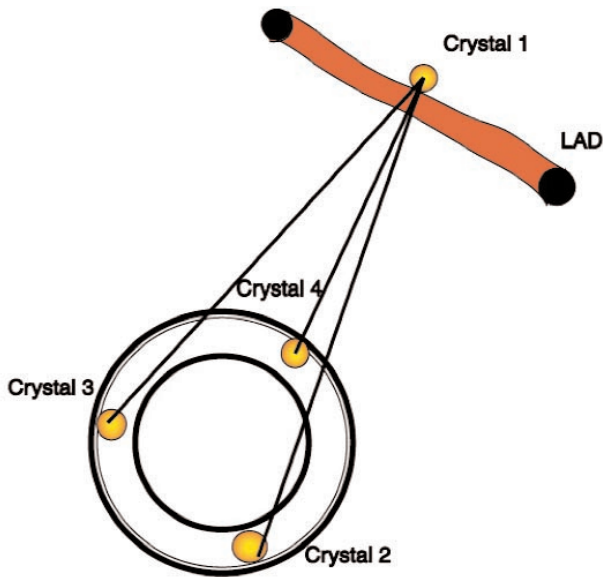


Figure 1. Schematic illustration of the fixed crystal ring demonstrating crystal labels and location relative to the left anterior descending artery (LAD) crystal.

artery (LAD) in 3-D space and to quantify via 3-D digital sonomicrometry the stabilization afforded by the use of a commercially available mechanical stabilizing arm.

## METHODS

### Surgical Preparation

Yorkshire swine ( $n = 7$ ; weight, mean  $\pm$  SD,  $65.5 \pm 6.7$  kg) purchased from Pork Power Farms (Turlock, CA, USA) were used in this study. Animals were treated in a humane manner in compliance with the Principles of Laboratory Animal Care formulated by the National Society for Medical Research and the *Guide for the Care and Use of Laboratory Animals* [DHHS 1985].

Animals were sedated with tiletamine-zolazepam (Telazol; 8 mg/kg, subcutaneously), intubated, and mechanically ventilated with 100% oxygen. Isoflurane gas (0.5%-4%) was used to maintain anesthesia. Amiodarone was administered at a rate of 0.25 mg/min to minimize ventricular irritability. A right groin incision was performed, and femoral arterial and venous cannulations were performed. A midline neck incision was made, and a 9F introducer catheter (Arrow International, Reading, PA, USA) was placed under direct vision into the right internal jugular vein. A continuous cardiac output Swan-Ganz catheter (Baxter Healthcare, Irvine, CA, USA) was introduced into the pulmonary artery through the right internal jugular vein and connected to a Vigilance monitor (Baxter Healthcare) for determinations of continuous cardiac output. A median sternotomy was performed, and a CTS Ultima sternal retractor (Guidant, Cupertino, CA, USA) was placed. The pericardium was opened in the midline and suspended via attachment to the chest wall to create a cradle. Fluid-filled catheters were then placed into both atria and

into the right ventricle for pressure monitoring with a Space Labs Vitatek 551 monitor (Squibb Vitatek, Hillsboro, OR, USA). A stab incision was made in the left ventricular apex, and a 3F Millar catheter (Model SPR-524; Millar Instruments, Houston, TX, USA) precalibrated in saline was inserted approximately 10 cm into the left ventricle. Left ventricular pressure was transduced with a Millar transducer (Model TC-510; Millar Instruments) and displayed with a Space Labs Vitatek 551 monitor. An analog-to-digital converter was used to integrate the monitor with a personal computer program (SonoLab, version 2.2.0; Sonometrics Corporation, Ontario, Canada) for all subsequent data acquisition, processing, and storage. Sonomicrometry data were collected over a sampling range of 193.05 Hz to 992.06 Hz. At this point in the procedure, baseline hemodynamic measurements were obtained for arterial and pulmonary blood gases, heart rate, cardiac output, and systemic, pulmonary, and cardiac chamber pressures. Stroke volumes and mean pressures were also calculated.

### Digital Sonomicrometry

A 2-mm diameter sonomicrometry crystal was sutured with 7-0 polypropylene (Prolene) suture (Ethicon, Somerville, NJ, USA) to the epicardial tissue adjacent to the LAD approximately 2 cm distal to the takeoff of the first diagonal artery. Care was taken to ensure that no diagonal branches were directly adjacent to the crystal. An acrylic (Plexiglas) ring with 3 crystals fixed in an equilateral triangle was placed into the pericardial sinus (Figure 1) with the heart resting directly on top of the crystals. Baseline sonomicrometry measurements were obtained over a 15-second period, during which ventilation was held to prevent motion artifacts. The Ultima stabilizing arm was then applied to the anterior surface of the heart with the foot positioned over the LAD artery and with the crystal exposed (Figure 2) according to

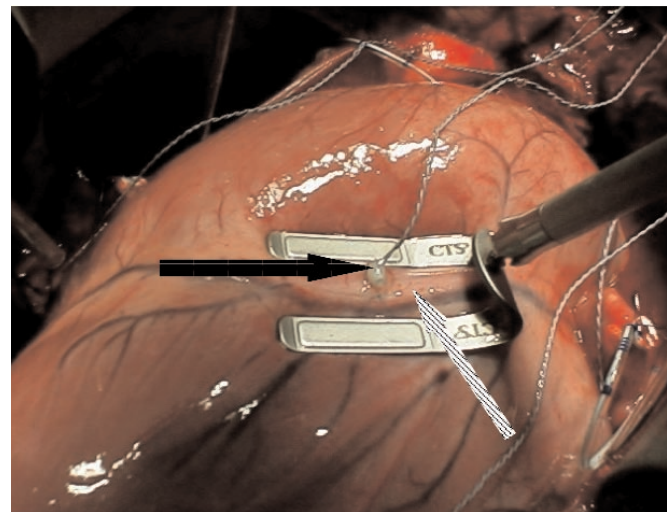


Figure 2. Intraoperative photograph illustrating sonomicrometry crystal placement (black arrow) and the application of the stabilizer foot around the left anterior descending artery (striped arrow).

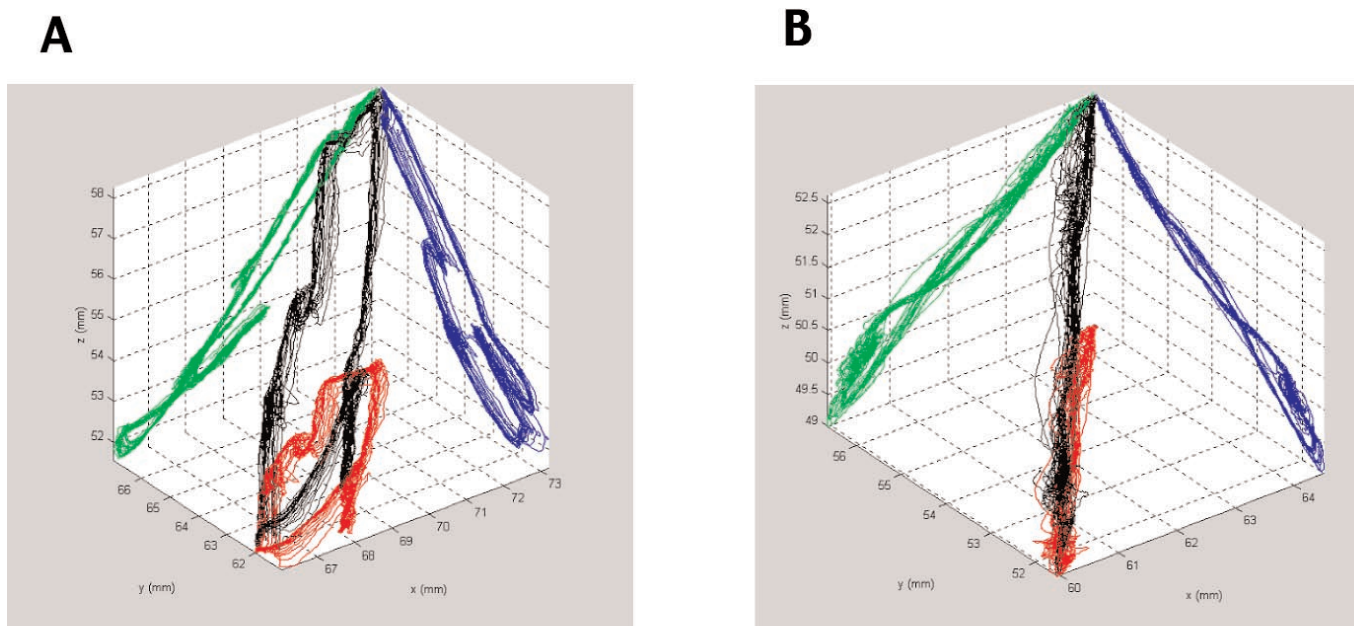


Figure 3. Three-dimensional plots of crystal motion in space in the x, y, and z planes (red, blue, and green, respectively, online) before (A) and during (B) stabilization. Black plots represent the summation vector (Cartesian motion) of crystal motion.

the technique previously described by Boonstra and colleagues [Boonstra 1997]. The arm position was fixed when stabilization appeared adequate for the performance of a beating heart anastomosis. To minimize operator variation, the same surgeon (M.L.K.) placed the stabilizer on each of the 7 animals. Once satisfactory stabilization was confirmed, the arm was left in place for 15 minutes. After 10 minutes, ventilation was held, and a 15-second sonomicrometry trace was obtained. Hemodynamic parameters were obtained after the arm was in place for 15 minutes. After the study was completed, the animals were humanely euthanized with an intravenous overdose of potassium chloride.

### Trace Analysis

Sonomicrometry data collected during the experiments were converted to binary form for transfer into SonoVIEW (version 10.0) for filtering. Traces were filtered for noise by means of computer-based criteria. Trace data were then transferred into SonoXYZ (version 1.0.12) for conversion to planar data. This transformation is based on the relationship between the LAD crystal and each of the embedded crystals representing a fixed coordinate plane. Crystals were assigned to the spatial locations of the origin (crystal 4), the x-axis (crystal 3), the x-y plane (crystal 2), and the positive-z quadrant (LAD, crystal 1) (Figure 1). The coordinates of the crystals in planar space were determined with a least squares algorithm in the SonoXYZ program. Data were expressed as distance for each point in time in each plane (x, y, and z), relative to the origin (crystal 4), and distances therefore approximated the diameter of the heart. Planes were defined relative to the operator with the z-axis being vertical, the x-axis being transverse, and the y-axis being sagittal.

The left ventricular pressure wave and the first derivative of the left ventricular pressure ( $dP/dt$ ) were used to find the time points of end diastole, and each beat was isolated. The excursion for each plane was defined as the maximum distance traveled by the LAD crystal in planar space, such that for each heartbeat the average excursion was defined as:  $\Sigma(d_{\max} - d_{\min})/n$ , where  $d_{\max}$  is the furthest distance traveled by the LAD crystal away from the origin,  $d_{\min}$  is the minimal distance traveled over the course of the crystal motion relative to the origin, and  $n$  is the number of beats during the 15-second data acquisition time. Velocity was determined with the equation,  $v = (d_2 - d_1)/(t_2 - t_1)$ , for each point in each plane and represented the instantaneous first difference. Maximal velocities in each plane over each beat were calculated and averaged, as was the average velocity per beat. Compression of the left ventricle occurring due to stabilizer placement was measured by determining the difference between the planar distance in the z plane at the point of end diastole during stabilization and the distance at baseline. This distance represents the amount of downward deformation of the heart occurring from the application of the stabilizer.

Cartesian excursion was defined as the average maximum observed distance between LAD Cartesian positions  $p(k) = [px(k), py(k), pz(k)]$  over a beat such that  $\text{Excursion} = \max(j, k \text{ in beat}) \sqrt{[px(j) - px(k)]^2 + [py(j) - py(k)]^2 + [pz(j) - pz(k)]^2}$ . This equation represents a combined vector of all 3 planes such that motion in space is not confined by the original planar boundaries dictated by the location of the fixed ring, thus allowing objective comparison between animals given slight variations in the relationship of the ring to the heart and the LAD crystal (Figure 3). The maximum and average of the Cartesian velocity magnitude,  $v = \sqrt{vx^2 +$

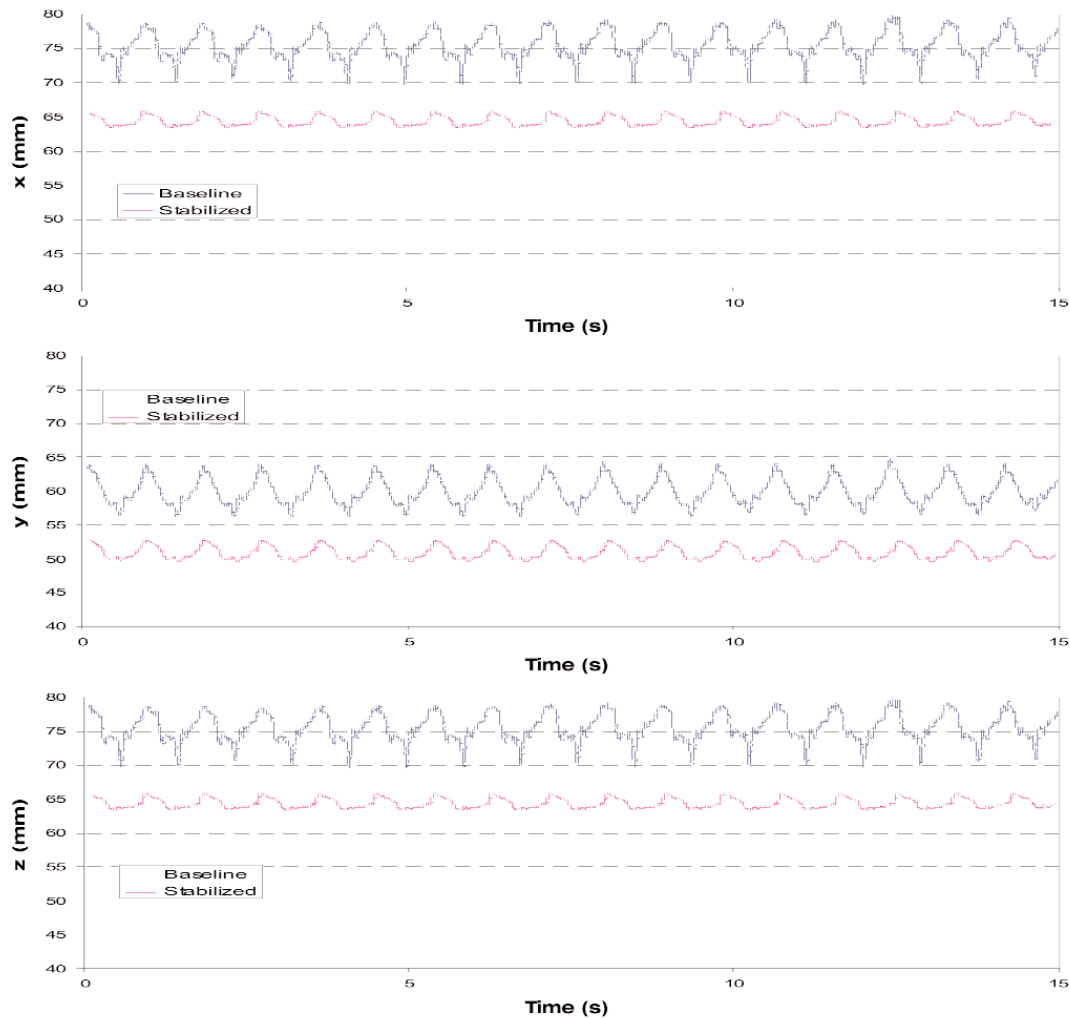


Figure 4. Plots of planar motion in the x, y, and z planes before (blue online) and during (pink online) stabilization demonstrating the complex, biphasic motion at baseline that is reduced to a lower-amplitude, monophasic pattern.

$v_y(2) + v_z(2)$ ], were also calculated for each trace sequence and averaged. Percent changes were calculated for both excursion and velocity. All mathematical manipulations were performed with custom software written for the MATLAB computer program (version 5.3.1; The MathWorks, Natick, MA, USA). Statistical analysis was performed for each parameter with the paired Student *t* test.

## RESULTS

All 7 animals survived to the completion of the study. There were no intraoperative complications associated with catheter placement, sternotomy and cardiac exposure, or stabilizer placement. No cardiac arrhythmias occurred during stabilization or during catheter placement.

### Changes in Cardiac Motion

Analysis of the LAD motion in planar space demonstrated a biphasic pattern in all 3 planes at baseline (Figure 4). This pat-

tern represents isolated planar motion in space of the normal, unrestrained beating heart. Application of the stabilizer arm dampened the motion of the LAD to a monophasic pattern with a visibly less steep rate of rise (velocity) (Figure 4). This pattern appeared to be consistent for all 7 animals studied.

### Planar Motion

Values for excursion, maximum velocity, and average velocity were tabulated for each heartbeat and then averaged for each animal. Standard deviations within animals were low because most beats occurring in the 15-second acquisition time were nearly uniform. Because of this uniformity, we compared the average values for each variable of each animal at baseline against the corresponding values during stabilization. Baseline excursion in the x, y, and z planes was  $6.98 \pm 1.62$  mm,  $6.47 \pm 1.12$  mm, and  $7.90 \pm 1.82$  mm, respectively (Table 1). After application of the stabilizer arm, the excursion was reduced to  $2.73 \pm 0.64$  mm,  $3.48 \pm 0.89$  mm, and  $3.99 \pm 1.32$  mm for the x, y, and z planes, resulting



Table 1. Comparison of Planar Excursion, Maximum Velocity, and Average Velocity at Baseline and at Stabilization

	Excursion, mm			Maximum Velocity, mm/s			Average Velocity, mm/s		
	X	Y	Z	X	Y	Z	X	Y	Z
Baseline	6.98 ± 1.62	6.47 ± 1.12	7.90 ± 1.82	92.66 ± 38.30	89.09 ± 38.23	92.27 ± 13.29	22.82 ± 4.54	22.36 ± 6.06	24.61 ± 3.83
Stabilized	2.73 ± 0.64	3.48 ± 0.89	3.99 ± 1.32	49.58 ± 20.38	51.80 ± 12.82	56.61 ± 22.28	8.99 ± 2.02	11.55 ± 3.09	12.47 ± 3.60
P, stabilized versus baseline	.0004	.003	.001	.014	.042	.014	.0001	.013	.0002

in a reduction of planar excursion by  $59.7\% \pm 11.1\%$  ( $P = .004$ ),  $43.8\% \pm 22.4\%$  ( $P = .003$ ), and  $48.3\% \pm 17.5\%$  ( $P = .001$ ), respectively. The compression of the heart in the z-axis at the point of end diastole was  $13.12 \pm 5.17$  mm.

There was also a large decrease in the maximum velocity of the LAD crystal in space. Maximum velocity represents the greatest instantaneous velocity of the LAD crystal at any point in the cardiac cycle and was calculated as an absolute value. The maximal velocity in each plane was reduced by  $42.9\% \pm 26.5\%$  (x;  $P = .014$ ),  $34.2\% \pm 29.7\%$  (y;  $P = .042$ ), and  $37.1\% \pm 27.1\%$  (z;  $P = .014$ ). Absolute values are shown in Table 1. The average velocity, also based on the absolute velocity vector, was determined and was significantly reduced in each plane. The average velocity diminished by  $59.9\% \pm 9.8\%$  (x;  $P = .0001$ ),  $43.4\% \pm 28.1\%$  (y;  $P = .013$ ), and  $49.4\% \pm 13.3\%$  (z;  $P = .0002$ ) after placement of the stabilizer.

### Cartesian Motion

Planar motion and velocity represent coordinates relative to the orientation of the fixed crystal ring (origin, crystal 4). Cartesian vectors, representing the summation of distance and velocity vectors in space, were determined for each animal. There was a highly significant decrease in Cartesian planar excursion with a reduction of  $46.32\% \pm 14.27\%$  ( $P = .0005$ ) (Table 2). Cartesian maximal velocity decreased by  $37.45\% \pm 24.40\%$  ( $P = .008$ ), and Cartesian average velocity decreased by  $50.53\% \pm 14.01\%$  ( $P = .004$ ).

### Hemodynamics

Hemodynamic data were obtained prior to placement of the stabilizer and after 15 minutes of stabilization (baseline versus stabilized) (Figures 5A-5H). There was a trend toward a decreased cardiac output ( $5.1 \pm 0.8$  mL/min versus  $4.8 \pm 0.8$  mL/min;  $P = .10$ ) with the stabilizer in place with a slightly increased heart rate ( $73.6 \pm 4.2$  beats/min versus  $77.4 \pm 12.6$  beats/min;  $P = 0.64$ ) and a significant drop in calculated stroke volume ( $69.9 \pm 11.2$  mL versus  $63.4 \pm 12.9$  mL;  $P = .04$ ). Stabilization did not appear to significantly alter central venous pressure (CVP, right atrial pressure) ( $5.7 \pm 2.6$  mm Hg versus  $7.0 \pm 2.5$  mm Hg;  $P = .06$ ), mean pulmonary artery pressure (mPAP) ( $11.6 \pm 3.7$  mm Hg versus  $17.0 \pm 9.6$  mm Hg;  $P = .18$ ), left ventricular end-diastolic pressure (LVEDP) ( $8.7 \pm 1.3$  mm Hg versus  $9.4 \pm 1.3$  mm Hg;  $P = .52$ ), and mean arterial pressure (MAP) ( $58.1 \pm 5.1$  mm Hg versus  $55.5 \pm 9.0$  mm Hg;  $P = .17$ ). The average mixed venous oxygen saturation (SvO<sub>2</sub>) ( $78.2 \pm 3.8$  mm Hg versus  $76.4 \pm 4.2$  mm Hg;  $P = .14$ ) and arterial pH ( $7.468 \pm 0.02$  versus  $7.449 \pm 0.03$ ;

$P = .15$ ) did not change over the course of the experiment, indicating a lack of metabolic derangements.

## DISCUSSION

The role of OPCAB surgery in cardiac revascularization continues to expand as surgeons grow increasingly comfortable with the techniques and instruments available to stabilize the moving myocardium. Previous research focused on whether anastomoses performed on the beating heart were sufficiently accurate to approximate the patencies achieved using conventional stopped-heart bypass surgery [Diegeler 1999, Omeroglu 2000, Amano 2001]. Recently, investigators have focused on improving existing designs of the instruments available for assistance [Mack 1998], including expansion into the novel field of robotically assisted, closed-chest OPCAB [Falk 1999, Mohr 2001].

Until now, there have been no objective means of providing data to evaluate the degree of stabilization afforded by any of the stabilizing systems currently available. Furthermore, device companies lack a benchmark technique for comparing designs of novel devices or for evaluating prototypes. By employing the well-known technique of sonomicrometry data acquisition, we have created a method of evaluating the motion of the LAD in 3-D space that can objectively determine the reduction in planar and Cartesian excursion, maximum velocity, and average velocity. These data were obtained while we carefully monitored the hemodynamic consequences of the maneuvers to balance stabilization with the required maintenance of adequate systemic perfusion.

The data from this study quantify the motion of the LAD in planar 3-D space, which represents the operative target of the surgeon. The crystal is small enough to be placed on the LAD, and the movement of this region must be taken into account when trying to isolate the artery and performing an anastomosis. The data indicate that at baseline there is a wide

Table 2. Cartesian Vector Values before and after Stabilization

Cartesian Values	Excursion, mm	Maximum Velocity, mm/s	Average Velocity, mm/s
Baseline	11.36 ± 1.74	141.80 ± 29.73	44.30 ± 7.02
Stabilized	5.99 ± 1.30	86.55 ± 29.45	21.46 ± 4.54
P, stabilized versus baseline	.0005	.008	.004

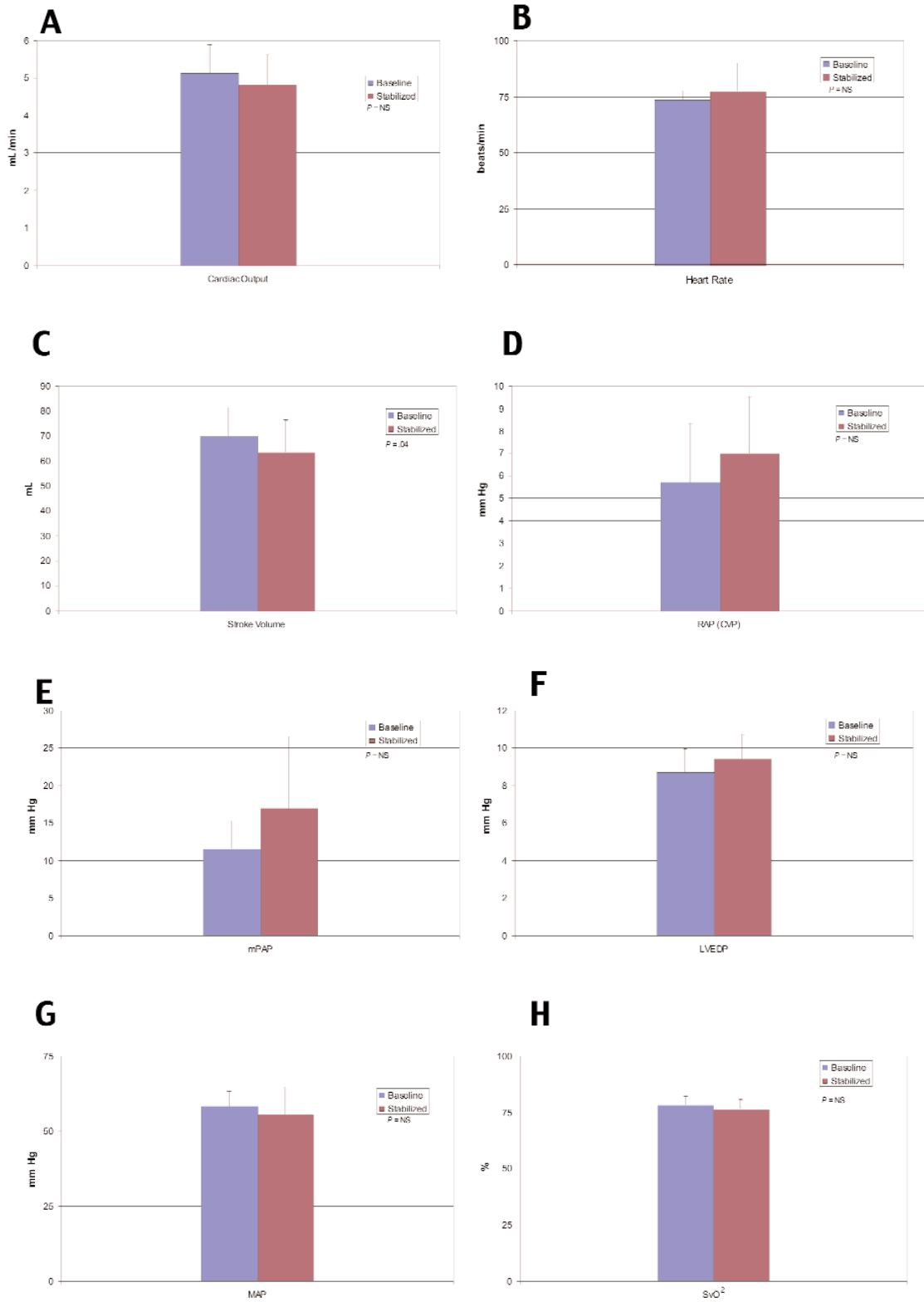


Figure 5. Graphs of hemodynamic parameters measured at baseline (blue online) and during stabilization (red online) for cardiac output (A), heart rate (B), stroke volume (C), right atrial pressure/central venous pressure (RAP/CVP) (D), mean pulmonary artery pressure (mPAP) (E), left ventricular end-diastolic pressure (LVEDP) (F), mean arterial pressure (MAP) (G), and mixed venous oxygen saturation (SvO<sub>2</sub>) (H). See text for values.

range of motion with which the surgeon must contend. The crystal moved by approximately 6 to 7 mm in each plane throughout the course of a beat, which occurs at a rate slightly faster than once per second. When one looks at the velocities involved, the problem becomes even more daunting. At one point in the cardiac cycle, the LAD is moving at approximately 90 mm/s (maximum velocity) in each plane. The average velocity in each plane is approximately 22 mm/s. An important qualification to these data is that they represent the absolute velocity and do not imply direction relative to any plane. Therefore, the degree of motion over the period of the complex cardiac cycle may be enormous at baseline. Cardiac motion is derived from the orientation of the fibers that bring about a torsional movement that effectively wrings blood from the ventricle. This torsional movement results in the high degree of motion seen in each plane.

Although myocardial revascularization surgery has been performed on nonstabilized beating hearts [Kolessov 1967], most surgeons are wary of trying to reproduce the patency rate achieved in arrested heart surgery in this type of surgical situation. It is for this specific reason that the development of stabilizer devices has been pioneered in the last 10 to 15 years. The application of one type of these devices, the CTS Ultima, significantly reduced the amount of excursion, the maximum velocity, and the average velocity of the LAD crystal by approximately 50% and also appeared to decrease the unquantifiable complexity of the motion. This stabilization appears to represent the degree necessary for the safe performance of coronary surgery. However, there remains a residual motion of 2 to 3 mm in each plane, as well as a maximum velocity of 50 mm/s and a range of average velocities from 9 to 12 mm/s. These findings suggest that there remains room for improvement in stabilizer systems that may continue to improve the safety and efficacy of off-pump coronary procedures. This type of testing also allows a fair comparison of devices of similar design (new prototypes of existing models) or of completely different designs (ie, the Octopus II versus the CTS Ultima).

Stabilization without evaluating the physiological impact of the application of the stabilizing device ignores the critical interplay between cardiac motion dynamics and the maintenance of adequate systemic perfusion. Previous reports have carefully verified the ability of the animal heart [Borst 1996, Grundeman 1997, Jansen 1997b, Burfeind 1998, Grundeman 1998a, Grundeman 1998b, Grundeman 1999] and the human heart [Jansen 1997a, Nierich 2000] to maintain adequate cardiac outflow during several maneuvers essential for the performance of complete myocardial revascularization. We monitored hemodynamic parameters (cardiac output, heart rate, stroke volume, LVEDP, mPAP, CVP) as well as indices of systemic perfusion (MAP, SvO<sub>2</sub>, arterial pH) to verify that our attempts to maximize LAD stability with the stabilizer device, although resulting in a minor reduction of stroke volume, did not significantly impinge on overall cardiac function. To achieve a degree of stability that appeared representative of that seen in the clinical setting, we did have to compress the heart by approximately 1.3 cm with the rigid arm of the CTS Ultima retractor system. Previous studies have shown

similar physiological changes, and this observed degree of compression and alteration in stroke volume is in line with the reports of other authors [Grundeman 1997, Diegeler 1998]. However, any study in animals must be evaluated with the understanding that they are otherwise healthy and young with a large degree of cardiac reserve and that the outcomes with such animals may not represent those seen in older human patients with significant myocardial dysfunction.

Whether this technique allows the objective comparison of stabilizing devices remains to be seen. This approach, especially with the inclusion of Cartesian vectors to eliminate the small differences among animals in the placement of the fixed ring, should allow a valid study. The degree to which these data will aid the practicing surgeon may be debatable, because most surgeons will develop subjective preferences for one system over another. However, this methodology may aid in the subsequent improvement of existing designs. With the new trend of robotically assisted devices and the need for minimal-access stabilizer systems, the need for this type of information becomes even more critical to the subsequent development of safe and effective surgical instruments. Future studies will also be focused on the degree of stabilization afforded to other coronary arteries, such as the posterior descending artery, the obtuse marginal branches, and the right coronary artery. There are some practical limitations to this technique because the fixed ring must remain in direct contact with the myocardium at all times and the sound waves emitted from the crystals must pass through water-based material to maintain communication. The LAD is the ideal target vessel for this initial study because the force of gravity maintains a fixed contact between the ring and the heart. These limitations may be easily overcome by employing a fixation technique to secure the ring next to the heart and liberally using a conducting medium such as ultrasound gel.

In summary, by using the highly sensitive technique of sonomicrometry, we were able to develop a method that allows the precise quantification of LAD artery motion in 3-D space before and after the application of a stabilizing arm. We have demonstrated significant reductions in the complexity of motion, the amount of motion in the planar space, and the velocity of the LAD after application of a stabilizer intended for OPCAB surgery.

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