

# Off-Pump Arterial Revascularization Using a New Reusable Device for Coronary Occlusion and Local Stabilization

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## ABSTRACT

**Background:** Optimal local stabilization, an unobstructed view, and a free field for operation are of most importance during off-pump surgery to facilitate high-quality anastomoses. We report on a new reusable stabilizing platform for complete off-pump coronary revascularization.

**Methods:** From May 2001 until June 2002, 118 consecutive patients (82 men, 36 women) with coronary artery disease (61 with 1-vessel, 42 with 2-vessel, and 15 with 3-vessel disease) and a mean age of  $63.6 \pm 10.0$  years (range, 41-88 years) were scheduled for complete off-pump arterial revascularization. The mean left ventricular ejection fraction was  $56.5\% \pm 12.5\%$  (range, 25%-85%). Exposure of the coronary vessels was facilitated with deep pericardial slings. The target coronary vessel was snared twice with air-cushioned silicone loops and fixed to the platform, which was connected to a flexible steel arm. The platform is available in 3 versions with different connector angles to accommodate various anatomical conditions. Together with its flat design, the platform provides an unobstructed view and a free field of operation.

**Results:** All operations were performed without any intraoperative complications, and all planned bypasses were carried out. The mean number of bypass grafts was  $1.7 \pm 0.8$  (range, 1-5). There was no early (30 days) mortality. The postoperative course was uneventful in all patients except for 1 reexploration for retrosternal bleeding, 10 patients with temporary atrial fibrillation, and 1 patient with reintubation after early extubation in the operating room because of respiratory insufficiency. Patients were discharged from the hospital in good condition  $8.7 \pm 2.6$  days (range, 5-18 days) after surgery.

**Conclusions:** Our data indicate that complete arterial off-pump revascularization can be performed safely and effectively

with a new reusable platform that provides excellent stabilization and an unobstructed view to the target coronary vessels.

## INTRODUCTION

Local stabilization appears to be of most importance during off-pump surgery to facilitate high-quality anastomoses. At the same time, an unobstructed view and a free field for operation are of great importance. Several investigators have reported good clinical results with off-pump revascularization using different types of stabilizing devices. Most of these devices are disposable [Cohn 1999, Kappert 1999, Spooner 1999, Hart 2000, Roy 2001]. We recently reported on the reusable Mid-coast system (Aesculap, Tuttlingen, Germany) [Riess 1999] as a stabilizing device for coronary revascularization of the left anterior wall. Its special design limits the use of this device to the revascularization of coronary arteries of the anterior wall, and it is less useful for revascularization of posterior coronary arteries. Therefore, we developed a new reusable platform with the same technique of coronary occlusion and stabilization to facilitate complete off-pump revascularization. We report on our initial experience with this device.

## MATERIALS AND METHODS

### Patients

From May 2001 until June 2002, 118 consecutive patients with coronary artery disease underwent complete off-pump coronary artery bypass grafting. Demographic data are presented in Table 1. Inclusion criteria for recruitment to the study were isolated coronary 1-, 2-, or 3-vessel disease considered suitable for complete off-pump coronary artery revascularization. Further inclusion criteria to the study group were severe concomitant diseases, such as kidney dysfunction, insulin-dependent diabetes mellitus, calcification of the ascending aorta, chronic obstructive pulmonary disease, arterial vascular disease, neurologic diseases, or malignancies. Significant concomitant noncardiac diseases (n = 66) were present in 52 of the 118 patients (Table 2).

### Anesthesia

Anesthesia in off-pump patients was induced with a bolus of propofol and sufentanil or remifentanil and maintained with a continuous intravenous infusion of propofol

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Table 1. Demographic Data of 118 Patients Who Underwent Off-Pump Revascularization with a New Reusable Stabilizing Platform\*

Patients, n	118
Male/female sex, n	82/36
Age, y	63.6 ± 10.0 (41-88)
Height, cm	174.2 ± 8.4 (142-193)
Weight, kg	78.7 ± 15.1 (42-125)
LVEF, %	56.5 ± 12.5 (25-85)
Coronary artery disease, n	
1-vessel	61
2-vessel	42
3-vessel	15
Main stem stenosis, n	8
Previous PTCA/stenting, n	42/30
Emergency operation, n	3

\*Data are presented as the mean ± SD (range) where appropriate. LVEF indicates left ventricular ejection fraction; PTCA, percutaneous transluminal coronary angioplasty.

and sufentanil or remifentanil. Intubation was facilitated with a single-bolus injection of pancuronium bromide. Standard monitoring included automatic ST-segment analysis. Swan-Ganz catheter monitoring was used only in patients with a left ventricular ejection fraction (LVEF) of less than 45%.

**Surgery**

After a limited skin incision and full sternotomy (n = 114) or an inverse L-shaped ministernotomy up to the third intercostal space (n = 4), unilateral or bilateral internal mammary arteries (IMA) were harvested under direct vision. Maximal vasodilatation of the left IMA (LIMA) was achieved by the topical application of papaverine. Exposure of the posterior coronary vessels was facilitated with deep pericardial slings. After the administration of heparin (150 IU/kg body weight), the target vessel was snared twice with a blunt needle and air-cushioned silicone loops (Genenzyme, Allen, TX, USA). For temporary coronary occlusion and local stabilization, a reusable platform

Table 2. Concomitant Diseases (n = 66) in 52 of 118 Patients Who Underwent Off-Pump Revascularization with a New Reusable Stabilizing Platform

Disease	No. of Patients
Peripheral arterial disease	14
Renal impairment	11
Chronic obstructive pulmonary disease	10
Carotid artery stenosis	9
Neurologic diseases	8
Diabetes mellitus (insulin dependent)	7
Dialysis	3
Calcification of ascending aorta	2
Malignancy	2

with 3 different connector angles (60°, 100°, 170°) (Geister, Tuttlingen, Germany) was used in combination with a flexible steel arm (Estech, Danville, CA, USA) (Figure 1). After 5 minutes of vessel occlusion followed by another 5 minutes of reperfusion, the coronary vessel was occluded again (Figures 2 and 3). The anastomosis between the coronary vessel and the graft vessel was performed with a running 8-0 monofilament suture on the beating heart without the use of cardiopulmonary bypass. Preconditioning was used if severe ischemia occurred during test occlusion of the coronary vessel. The first preference for graft vessels was both IMA. Additional saphenous vein or radial artery grafts were used in 4 patients. IMA grafts were performed as in situ bypasses and as T grafts, including jumping bypasses and Y bypasses. A 50% heparin reversal was performed by protamine.

**Postoperative Management**

Extubation was achieved on the operating table or early in the postoperative period. Postoperative anticoagulation therapy with unfractionated heparin was administered intravenously

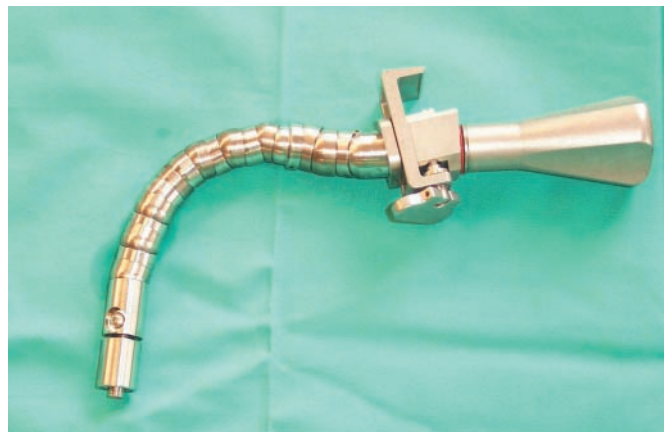
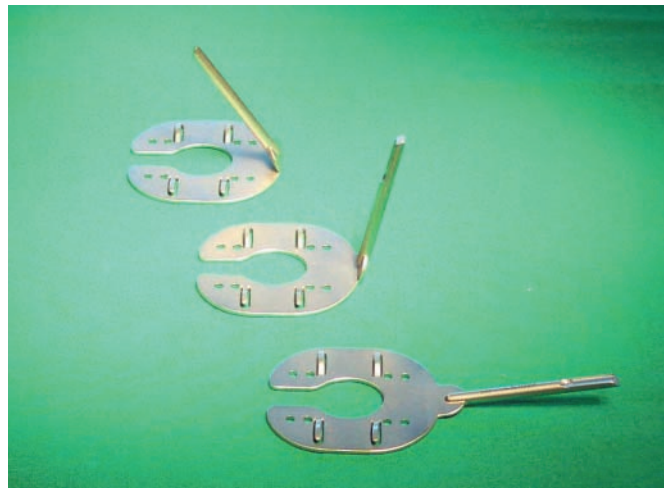


Figure 1. The 3 versions of the stabilizing platform with different connector angles to accommodate various anatomical conditions (top) are used in combination with the Estech arm (bottom).

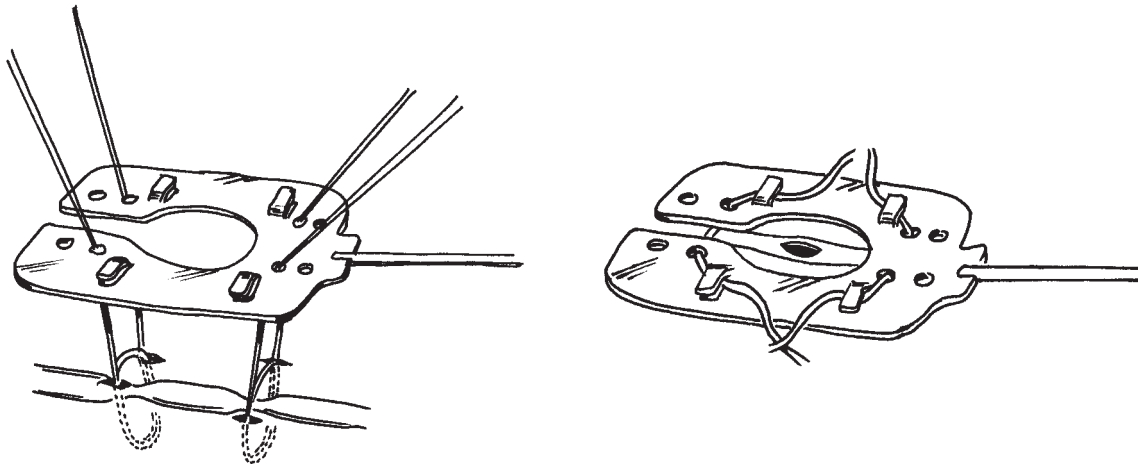


Figure 2. Principle of intermittent coronary occlusion and stabilization with a new reusable platform for complete coronary artery bypass revascularization. Positioning of the platform before (left) and after (right) coronary artery occlusion.

at a dosage of 100 IU/kg body weight per hour on the operative day and increased to 200 IU/kg body weight per hour on the first postoperative day. This treatment was followed with low-dosage heparinization therapy ( $2 \times 7500$  IU per day) until the patient was completely mobile. After an initial IV bolus of 500 mg acetylsalicylic acid 4 hours after the operation, all patients then received 100 mg acetylsalicylic acid per day, and clopidogrel was added in the case of a hybrid procedure with percutaneous transluminal coronary angioplasty and stent implantation.

### Statistics

All data are presented as the mean  $\pm$  SD.

## RESULTS

All operations were performed without intraoperative complications. Positioning of the heart by means of deep pericardial slings and local cardiac stabilization coupled with temporary coronary occlusion with a new platform were well tolerated in all patients, even in the cases of poor left ventricular function (LVEF  $<45\%$ ,  $n = 13$ ; LVEF  $<25\%$ ,  $n = 5$ ). There were no conversions to cardiopulmonary bypass (Table 3). Preconditioning was used in 1 patient for whom the ST-segment elevation was 4.3 mV. Minor ventricular arrhythmias during temporary occlusion of a coronary vessel occurred in only 10 of 118 patients and with no significant left ventricular dysfunction. The exposure of the heart for coronary artery revascularization via deep pericardial slings and the opening of the right pleural cavity were achieved in all cases without major hemodynamic impairment. Thus, all preoperatively planned coronary artery bypasses were carried out successfully. The mean number of bypass grafts was  $1.7 \pm 0.8$  (range, 1-5). Twenty-four T grafts were created with the right IMA (RIMA) as a free transplant to the in situ LIMA bypass before off-pump coronary artery revascularization. First, side-to-side or end-to-side anastomoses were performed to the marginal branches, the circumflex artery, and the distal right coronary arteries. Then, coronary vessels of the

anterior wall were bypassed with the LIMA as a single bypass to the left anterior descending coronary artery (LAD) ( $n = 88$ ) or as an LAD jump–diagonal branch bypass ( $n = 25$ ). In the case of in situ LIMA and RIMA bypasses, the marginal branches were anastomosed first, and the LAD was anastomosed second. The total numbers of bypasses and the kinds of coronary vessels bypassed are shown in Tables 4 and 5, respectively. Only 4 saphenous vein grafts and 1 radial artery graft were used in a total of 4 patients. Two saphenous vein grafts and the arterial graft were connected as a T graft to the LIMA bypass. In 1 patient, a proximal anastomosis to the ascending aorta was performed during tangential clamping of the ascending aorta, and in another patient, a proximal anastomosis was performed with the CorLink device (CardioVations, Somerville, NJ, USA) without side-clamping the aorta for an automatic anastomosis between the saphenous vein graft and the ascending aorta.

Early extubation in the operating room was performed in 69 patients (58.5%). The mean time of postoperative ventilation for the remaining 49 patients was  $4.6 \pm 3.7$  hours. The mean volume of postoperative blood and serous fluids lost in the off-pump group through the thoracic drainages was  $1118 \pm 460$  mL. No major complications occurred during the

Table 3. Intraoperative Data of 118 Patients Who Underwent Off-Pump Revascularization with a New Reusable Stabilizing Platform\*

Bypass anastomoses, n	188
Coronary occlusion time, min	$15.6 \pm 4.7$ (4-32); $n = 188$
ST-segment elevation, mV	$1.2 \pm 0.77$ (0.5-4.3); $n = 27$ (22.9%)
Minor ventricular arrhythmia, n	10 (8.5%)
Preconditioning, n	1 (0.9%)
Surgery time, min	$170.9 \pm 55.9$ (95-315)
Conversions to CPB	None
Extubation in operating room, n	69 (58.5%)

\*Data are presented as the mean  $\pm$  SD (range) where appropriate. CPB indicates cardiopulmonary bypass.

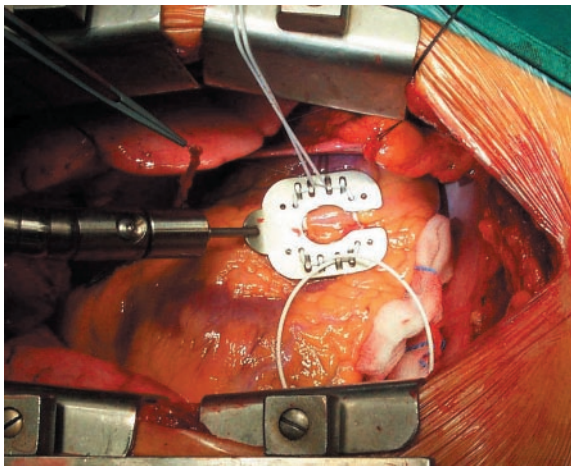
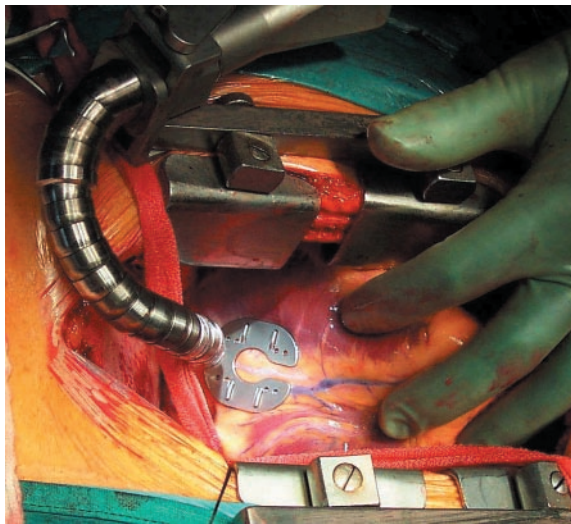
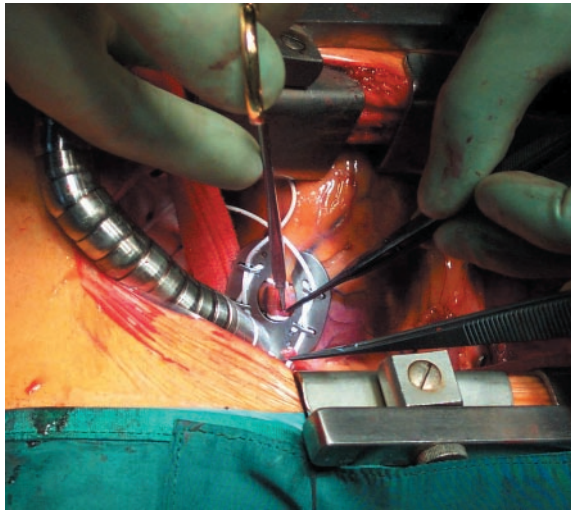


Figure 3. Intraoperative view during complete arterial off-pump revascularization using 3 types of a new reusable steel platform for coronary artery occlusion and local stabilization of the circumflex artery (top), posterior descending artery (middle), and the left anterior descending coronary artery (bottom).

postoperative course (Table 6). Catecholamine therapy was not necessary in any patient, even in the cases of impaired left ventricular function. Interestingly, no further deterioration of preexistent organ dysfunction was observed postoperatively. In 1 patient, a transient respiratory insufficiency observed on the first postoperative day required reintubation and ventilation for another 16 hours. Ten patients experienced temporary atrial fibrillation during the postoperative course. There was no hospital mortality (<30 days). A hybrid procedure consisting of a minimally invasive LIMA-to-LAD bypass and postoperative balloon angioplasty and stenting of an additional coronary stenosis was performed in 2 patients (Table 6).

## DISCUSSION

The most important advantage of beating heart surgery is that cardiopulmonary bypass with its multiple side effects on every organ system [Anderson 1991], including the lungs, kidneys, liver, and brain, is avoided [Chertow 1998, Izzat 1998, Kappert 1999, Spooner 1999, Riess 2000, Ricci 2001, Loef 2002, Patel 2002].

We report our early results in a heterogeneous group of patients with a new reusable platform that can be used in combination with a flexible arm for complete coronary artery revascularization. Because of its special design and metal body, the device provides a high degree of local stabilization of the target area. The relatively large size of the platform ensures atraumatic force distribution to the entire region of contact with the ventricle and decreases the risk for ventricular perforation, especially of the posterior wall, during coronary artery revascularization. The vessel loops can be opened and refixed in seconds. This completely reusable system decreases costs for the hospital. The platform is available in 3 versions with different connector angles (60°, 100°, 170°) that accommodate to various anatomical conditions. This property, together with the device's flat design, provides the surgeon with an unobstructed view and a free operation field.

Using this platform in combination with the flexible Estech arm, we revascularized all coronary arteries without any problems. In the case of bypass grafting to a marginal or a circumflex coronary artery, opening the right pleural cavity in combination with deep pericardial slings improved the exposure of the coronary vessel. In most cases, especially if a T graft between the LIMA and the RIMA was used, anastomoses between the RIMA and marginal branches, the

Table 4. Numbers of Bypass Grafts in 118 Patients Who Underwent Off-Pump Revascularization with a New Reusable Stabilizing Platform

Bypass Grafts per Patient, n	No. of Patients
1	65
2	40
3	10
4	2
5	1

Table 5. Coronary Vessels Bypassed in 118 Patients Who Underwent Off-Pump Revascularization with a New Reusable Stabilizing Platform

Coronary Vessel	Bypasses, n
Left anterior descending artery	114
Diagonal branch	23
Marginal branch	25
Circumflex artery	9
Posterolateral branch	2
Posterior descending artery	15
Total	188

circumflex artery, and the distal right coronary arteries were performed first to avoid stress to the LIMA bypass during exposure of the heart toward the right pleural cavity. Then, coronary vessels of the anterior wall were bypassed with the LIMA as a single LAD bypass in 88 patients and with an LAD jump–diagonal branch bypass in another 25 patients. In cases of in situ IMA bypasses, RIMA grafts to the LAD or marginal branches were performed first, and a LIMA bypass to the marginal branch or the LAD was performed second to avoid tension to the bypass grafts.

In most of the study patients (114/118), we used a complete sternotomy combined with limited skin incision, because in our experience total sternotomy results in less postoperative wound pain than partial sternotomy and anterior thoracotomy. Furthermore, not a single case of sternal wound infection has been seen to date in nearly 600 off-pump operations, and only 1 patient with sternum instability has been observed.

No early (<30 days) deaths or myocardial infarctions occurred in our study group. The mean number of coronary vessels revascularized in our study group was relatively small

Table 6. Postoperative Data of 118 Patients Who Underwent Off-Pump Revascularization with a New Reusable Stabilizing Platform\*

CKMB 4 h postoperatively, U/L	5.8 ± 11.4 (0-73)
Postoperative ventilation, h	4.6 ± 3.7 (1-16)†
Red cell transfusion, mL	635 ± 268 (300-1200); n = 10, 8.5%
Thoracic drainages, mL	1118 ± 460 (210-2360)
Postoperative hemoglobin, g/dL	12.2 ± 1.5 (8.0-15.2)
Postoperative hospital stay, d	8.7 ± 2.6 (5.0-18.0)
Hybrid case (PTCA of CFX or RCA), n	2 (1.7%)
Respiratory insufficiency	1 (0.9%)
Myocardial infarctions	None
Neurologic complications	None
Renal failure	None
Rethoracotomy for bleeding	1 (0.9%)
Temporary atrial fibrillation, n	10 (8.5%)

\*Data are presented as the mean ± SD (range) where appropriate. CKMB indicates creatine kinase–MB; PTCA, percutaneous transluminal coronary angioplasty; CFX, circumflex artery; RCA, right coronary artery.

†Mean value of 49 patients (41.5%) not extubated in the operating room.

[Patel 2002]. The reason for this result is that most patients who underwent off-pump surgery had 1- or 2-vessel coronary artery disease (Table 1).

Most interestingly, no further deterioration of preexistent organ impairment occurred during the postoperative course in patients who underwent revascularization with the off-pump approach. In particular, the absence of any renal dysfunction or cerebral strokes is in concordance with the results of randomized studies by other investigators, who described a significantly lower frequency of cerebral stroke [Ricci 2001, Patel 2002] and renal damage [Loef 2002] in patients who underwent off-pump coronary artery revascularization. Most patients (n = 69; 58.5%) were extubated in the operating room, and the postoperative ventilation time for the remaining 49 patients was only 4.6 ± 3.7 hours [Meharwal 2002, Patel 2002]. One patient who had undergone complete off-pump revascularization and extubation in the operating room developed transient respiratory insufficiency. This patient required early reintubation and ventilation for another 16 hours, after which the further postoperative course of the patient was without problems.

The total postoperative blood loss was relatively high. This finding is in contrast to that of Ascione et al [2001], who found a reduced postoperative blood loss after off-pump surgery. However, red cell transfusion was necessary in only 10 (8.5%) of 118 patients (Table 6), and atrial fibrillation also occurred in only 10 (8.5%) of 118 patients. These findings are in concordance with those of several investigators [Diegeler 1999, Meharwal 2002, Patel 2002] but in contrast to the results of other workers [Cohn 1999, Place 2002], who found a relatively high number of postoperative atrial fibrillation cases among patients who underwent off-pump coronary artery bypass grafting. Finally, due to reimbursement characteristics of the health care system, the lengths of hospital stays were relatively long compared with those reported by other investigators [Patel 2002]. The lengths of hospital stays may change in the near future with modifications occurring in our health care system, and these changes may result in a reduction of costs [Doty 1997]. A hybrid procedure was only performed in two cases because of severe calcification of the ascending aorta and the mitral anulus or deep intramural run of a circumflex artery, respectively. In these special situations a hybrid approach appears to be a helpful alternative to the complete arterial off-pump revascularization providing good midterm results [Riess 2002].

In summary, our data indicate that complete arterial off-pump revascularization can be performed safely and effectively with a new reusable platform that provides excellent stabilization and an unobstructed view of the target coronary vessel.

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