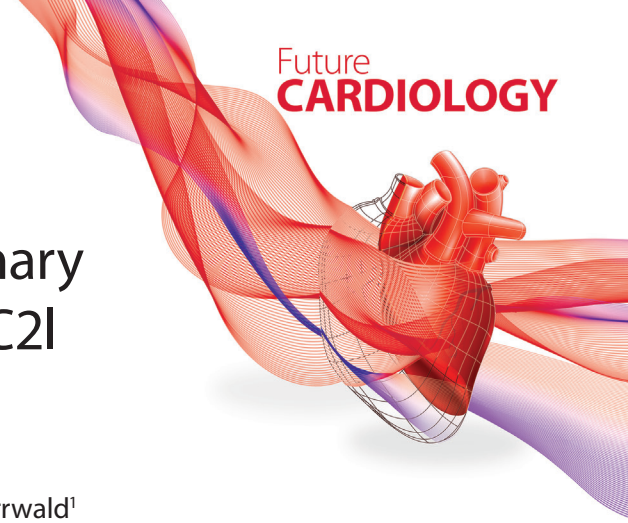
Future CARDIOLOGY



CASE REPORT

First high-risk percutaneous coronary intervention under use of the iVAC2l system in Germany

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Percutaneous coronary intervention of complex stenoses is becoming more and more of an alternative to coronary bypass surgery. Nevertheless, complications can occur and lead to the need for circulatory support and/or emergency surgery. Circulatory support devices like the intra-aortic balloon pump showed only low benefit in patients' outcome. Devices with higher cardiac output necessitate more complex implantation procedures. We report the case of the first successful use of a transfemoral pulsatile ventricular assist device with up to 2 l additional cardiac output during high-risk percutaneous coronary intervention in a 74-year-old man with complex stenosis. The device was safe and feasible during coronary intervention in its use. Its beneficial effect on hemodynamics and patients' outcome has to be evaluated in larger multicenter studies.

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KEYWORDS
• circulatory support • high-risk PCI • left ventricular assist device

Percutaneous coronary intervention (PCI) is a therapeutic alternative to coronary artery bypass grafting (CABG) in patients with coronary artery disease. Current guidelines recommend PCI also in patients with complex coronary stenosis like left main stenosis with high level of evidence [1]. Nevertheless, complication in high-risk PCI may lead to the need for extracorporeal circulation or emergency switch to CABG. To protect patients' circulation, and especially coronary circulation, during or after PCI procedures, several devices have been evaluated.

The use of intra-aortic balloon pump (IABP) is technically feasible for the interventionalist with unclear benefit for patient's outcome: although IABP use in cardiogenic shock failed to reduce 30-day mortality and showed no long-term benefit [2], several studies assumed a potential benefit in high-risk PCI [3–5].

The use of alternative circulatory assist devices guarantees an adequate circulation at the expense of a complex setting including technicians during PCI, which is often only available in tertiary care centers and shows higher rates of adverse events compared with IABP [6,7]. The implantation of a TandemHeart device (Cardiac Assist, PA, USA) is less complex, but it requires at least an interventional cardiologist who is familiar with the trans-septal puncture maneuver and it has more bleeding and ischemic complications compared with IABP because of the larger insertion cannulae [8].

Pulsatile devices like the iVAC3l system (PulseCath BV, Amsterdam, The Netherlands) are able to generate an additional cardiac output (CO) up to 3 l/min, but the insertion is complex and requires surgical support for preparation of the right subclavian artery access [9].

The iVAC2l device (PulseCath BV) is a new pulsatile ventricular assist device, which is able to generate an additional CO of up to 2 l/min [10]. It is inserted via a transfemoral access with placement of the 17 Fr, 100 cm long single lumen catheter in the left ventricular outflow tract via the aortic valve [10]. Blood is aspirated from the left ventricle through the catheter tip during the systolic phase and is directed back in the diastolic phase by the membrane pump to the ascending aorta

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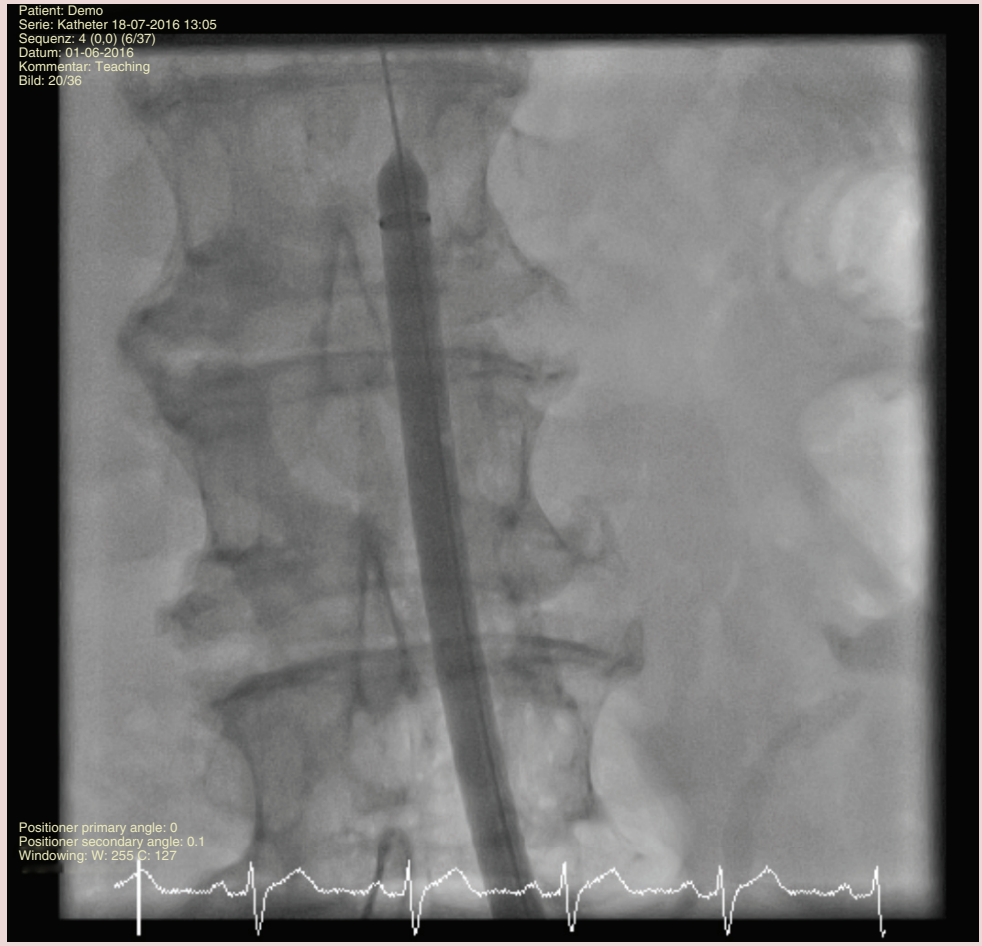

Figure 1. Inflated sheet in the left femoral artery and abdominal aorta.

via a two-way catheter valve [10]. The pulsatile function is steered by ECG or aortic pressure; In contrast to the Impella 2.5 system (ABIOMED, MA, USA) it is driven and compatible with conventional IABP consoles, which are still available in most catheter laboratories, and thus requires no additional technical equipment [8,10].

Case report

We report on the case of a 74-year-old man admitted to hospital after sudden cardiac arrest and concomitant cardiopulmonary reanimation over 10 min due to asystole. The patient had a history of coronary artery disease with a complex intervention of the right coronary artery and vessel dissection during PCI with the need for cardiopulmonary reanimation in the past and had a chronic obstructive pulmonic disease. Initial left ventricular ejection fraction was decreased to 42%. Peripheral artery disease was also assumed in the past but Doppler- and color-Doppler-ultrasound revealed no high-grade stenosis in femoral arteries. Coronary angiography revealed a distal 50% stenosis of the left main, a 90% ostial stenosis of the left circumflex artery (LCX), a 90% proximal stenosis of the anterolateral artery and a 50% proximal stenosis of left anterior descendent artery. The angiography of the right coronary artery showed no relevant stenoses and a good long-term result after complex intervention in the past. Ostial PCI of LCX was recommended. Because of the history of sudden cardiac arrest during PCI and at admission, and the severe chronic obstructive pulmonic disease, we decided to perform PCI under protection of iVAC2l in a second session to avoid anesthesia and oral intubation during CABG. After the patient gave written informed consent, we tried to get radial access on the right side but, due to an earlier coronary arteriography, we

were not able to place the access there. Therefore, we first placed a 6-Fr access on the left femoral artery and performed arteriography of the right-sided arteries in crossover technique. It revealed an eccentric calcified plaque in the right iliac artery. Therefore, we chose left femoral artery for access and inserted two ProGlide devices. We decided to place a SoloPath recollapsable 13.5-Fr access system via left femoral artery and inflated it to 19 Fr **(Figure 1)**. A 5-Fr anterolateral 1 guidance catheter was inserted over the aortic valve and a stiff wire was placed in the left ventricle. Via stiff wire, the 100 cm, 17-Fr single lumen bidirectional flow catheter was placed in the left outflow tract with the catheter tip in the left ventricle and the bidirectional ventile in the ascending aorta **(Figure 2)**. The device was connected to the IABP console (Maquet Cardiovascular, NJ, USA) and ECG-triggered pulsatile assist was started **(Figures 3 & 4)**. Pressure curves in aortic position showed the typical notches in diastolic phase assuming correct device function. After a couple of minutes with correct device function, we tried to place a 6-Fr JL4 guidance catheter via right femoral access, but the guidance catheter was not able to pass aortic bifurcation due to severe arteriosclerosis and the already placed device catheter. Therefore, we decided to perform PCI via left radial access. Intubation of the left coronary ostium with the guidance catheter was performed and coronary wires were placed in left anterior descendent artery, LCX and obtuse marginal artery. PCI with insertion of an ostial LCX drug-eluting stent and percutaneous coronary angioplasty of obtuse marginal artery was performed with excellent primary results **(Figure 5)**. The whole procedure was performed in a spontaneous breathing patient with

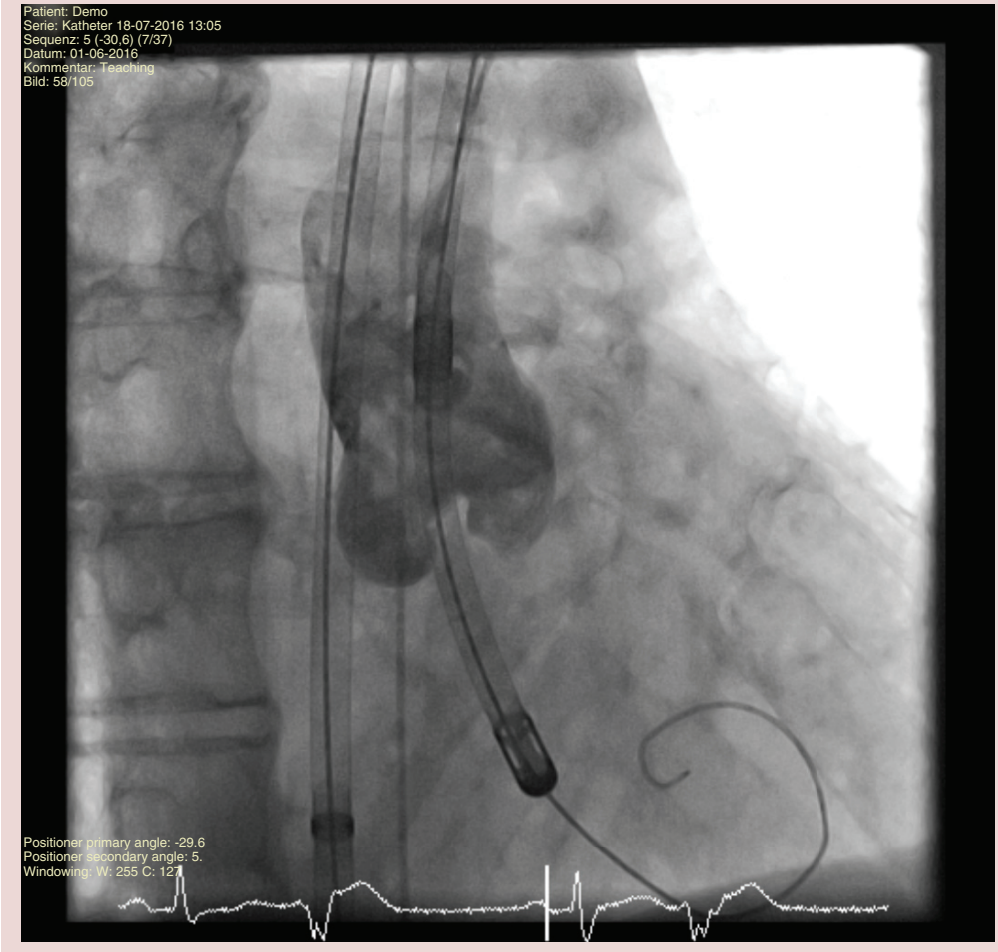

Figure 2. A stiff wire is placed in the left ventricle and the iVAC2l device is placed over the aortic valve.

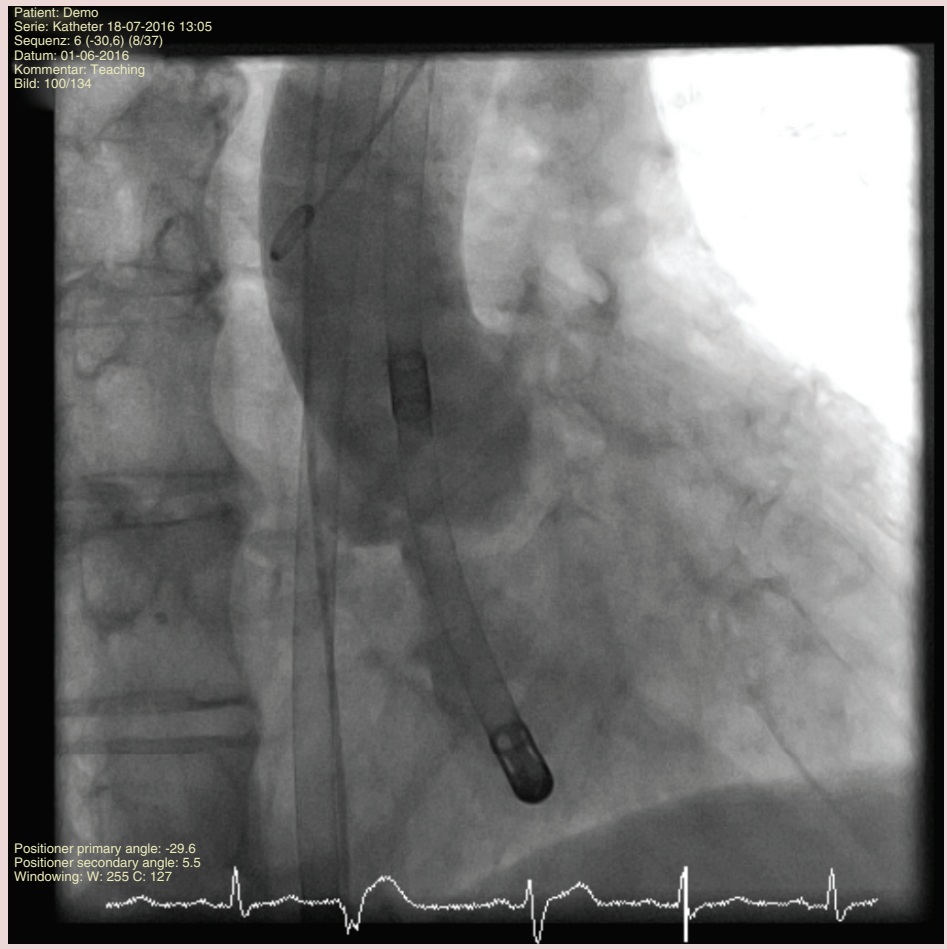

Figure 3. The device in its final position after the removement of the stiff wire.

only local anesthesia in the radial and femoral access areas and without the need for intravenous inotropic agents. After PCI, the device catheter was removed from the aorta, and transthoracic echocardiography was performed to exclude valve damage. The left femoral access was decollapsed and removed. The artery access was closed with the two ProGlide devices. The patient was observed on our intensive care unit until the next day; complications in the region of artery accesses or at aortic valve did not occur. The patient left our hospital 2 days later in good clinical condition.

Discussion

High-risk PCI is increasingly becoming an alternative to CABG [1]. The majority of surgical procedures are supported by extracorporeal circulation that guarantees sufficient blood flow. To achieve sufficient CO and coronary perfusion during PCI, several devices have been developed [11]. The IABP was assumed to increase coronary perfusion and to generate an additional CO up to 0.5 l/min. Nevertheless, it failed to show lower mortality rates or circulatory benefit in the IABP–SHOCK II trial [2], and no beneficial support was shown in a prophylactic implantation setting compared with stand-by use [3]. Data of the left ventricular assist device or extracorporeal membrane oxygenation support during high-risk PCI are sparse and the implantation of the devices is complex [11]. We report the first use of the iVAC2l by interventional cardiologists during high-risk PCI in Germany. During the whole procedure, the device worked correctly and via radial access we did not notice interactions with the guidance catheter. Caused by peripheral arterial disease, safe passage of abdominal aorta with inlying device access and catheter was not possible. Preinterventional imaging of abdominal aorta

and inguinal arteries should be recommended to avoid femoral access complications. The closure of the femoral access with a ProGlide device worked well, and no complications in the access area occurred. Postinterventional transthoracic echocardiography showed unimpaired valve function. Thus, we can assume a safe, feasible and easy use of the iVAC2l device in combination with the 13-Fr sheet and the ProGlide device during PCI. In contrast to the Impella 2.5 system, the iVAC2l system generates a comparable CO and requires only a standard IABP console that is still available in most catheter laboratories. The additional cardiac index is substantially lower compared with a conventional extracorporeal membrane oxygenation system or the TandemHeart but the implantation of the device is less complex without the need for cardiac technicians or additional trans-septal puncture maneuver [8].

Albeit the use of IABP during PCI was also safe, feasible and comfortable, it failed to show mortality or circulatory benefit for treated patients [2,3]. The iVAC2l device may be a useful and efficient alternative to the IABP system in patients with reduced left ventricular ejection fraction and/or reduced CO in PCI centers without local cardiac surgery and without access to extracorporeal membrane oxygenation devices to provide an additional CO comparable with the Impella 2.5 system and thus, a safe coronary intervention. Hitherto, the circulatory support and patients' benefit of the iVAC2l device need to be investigated in large multicenter studies.

Conclusion

The use of the iVAC2l system was safe and feasible in its use during percutaneous coronary

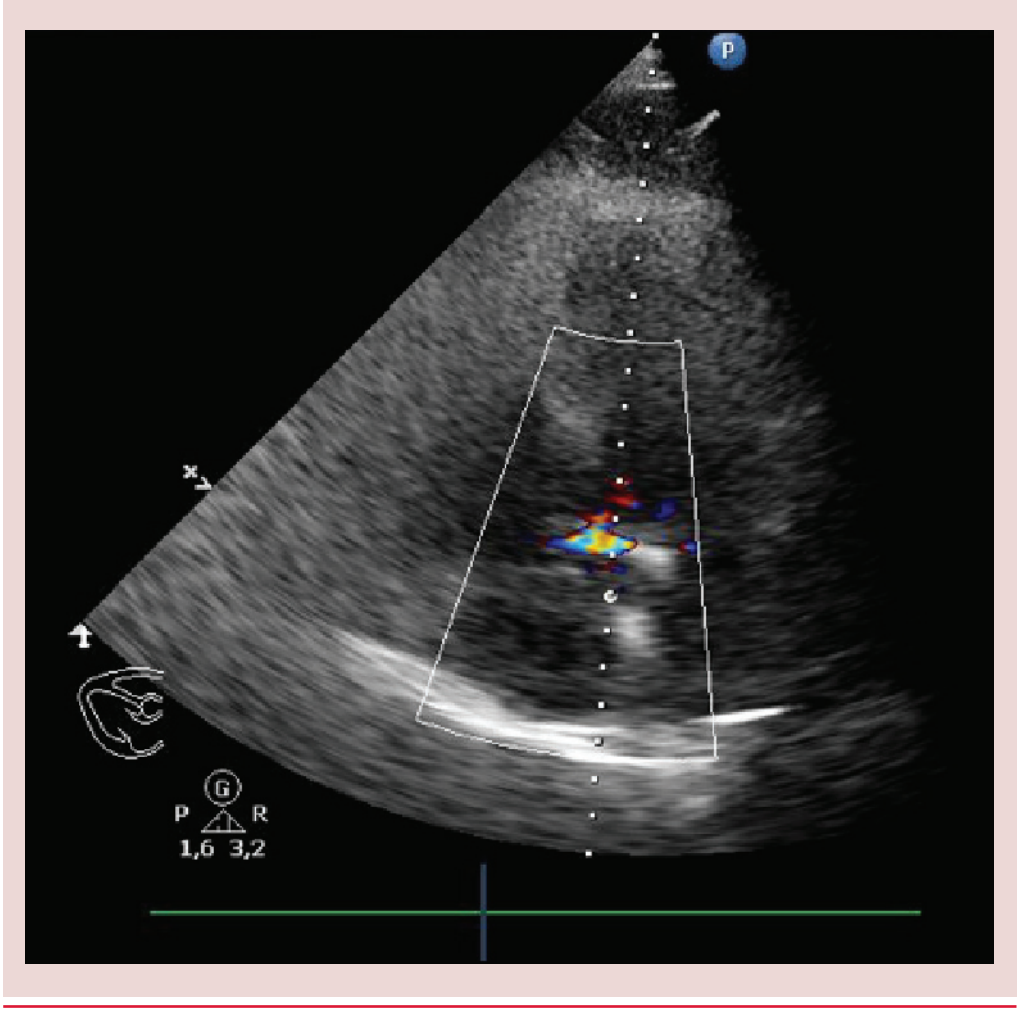

Figure 4. Color-Doppler signals of the diastolic ejection of the device in apical five-chamber view in transthoracic echocardiography.

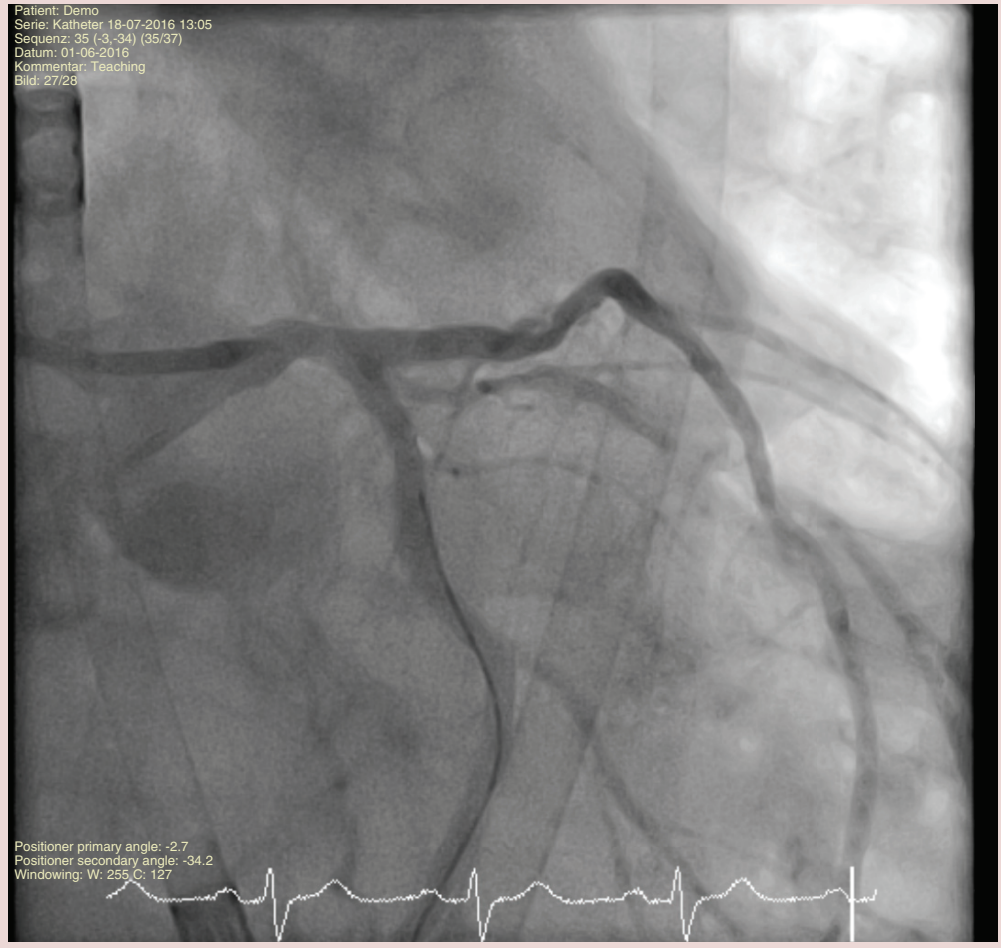

Figure 5. Angiographic results after intervention of the ostial left circumflex artery and the obtuse marginalis artery.

high-risk intervention. Nevertheless, the beneficial effect on hemodynamics and patients' outcome has to be evaluated in larger multicenter studies.

Financial & competing interests disclosure

The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials

EXECUTIVE SUMMARY

- Percutaneous coronary intervention (PCI) of complex stenoses is becoming more and more an alternative to coronary bypass surgery.
- Complication in high-risk PCI may lead to the need for extracorporeal circulation or emergency switch to coronary artery bypass grafting.
- Devices with higher cardiac output often necessitate more complex implantation procedures.
- Devices with a lower cardiac output but a less complex implantation procedure compared with extracorporeal membrane oxygenation may be an alternative in high-risk PCI.
- We performed successfully the first high-risk PCI in Germany under the use of the iVAC2l system.
- The device was safe and feasible in its use during PCI.
- Its beneficial effect on hemodynamics and patients' outcome has to be evaluated in larger multicenter studies.

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No writing assistance was utilized in the production of this manuscript.

Informed consent disclosure

The authors state that they have obtained verbal and written informed consent from the patient/patients for the inclusion of their medical and treatment history within this case report.

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