



Use of a Novel Pericardial Covered Stent to Seal an Iatrogenic Coronary Perforation

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ABSTRACT: Iatrogenic coronary perforation complicates 0.1–0.8% of percutaneous coronary interventional (PCI) procedures. The incidence is higher if atheroablative therapy is used. When coronary perforation occurs, it may rapidly result in cardiac tamponade, myocardial infarction or death, hence prompt treatment is required. PTFE-covered stents have been used to seal coronary perforations, but these are bulky devices that lack flexibility, and rapid deployment in calcified or tortuous vessels can be difficult, particularly in emergency situations. Furthermore, difficulties in achieving adequate stent expansion and the prospect of delayed re-endothelialization have led to concern about the increased potential for stent thrombosis or restenosis. We present the first report of the successful use of a novel, highly deliverable pericardial covered stent to treat an iatrogenic coronary perforation during PCI, with angiographic follow up.

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Iatrogenic coronary perforation complicates 0.1–0.8% of percutaneous coronary interventional (PCI) procedures.^{1–5} The incidence is higher (0.5–3%) if atheroablative therapy such as rotational or laser atherectomy is used.^{1,6,7} When coronary perforation occurs, it may rapidly result in cardiac tamponade, myocardial infarction or death, hence prompt treatment is required. Therapeutic measures include reversal of heparin, prolonged balloon inflation at the perforation site, deployment of a covered stent, or emergency cardiac surgery.

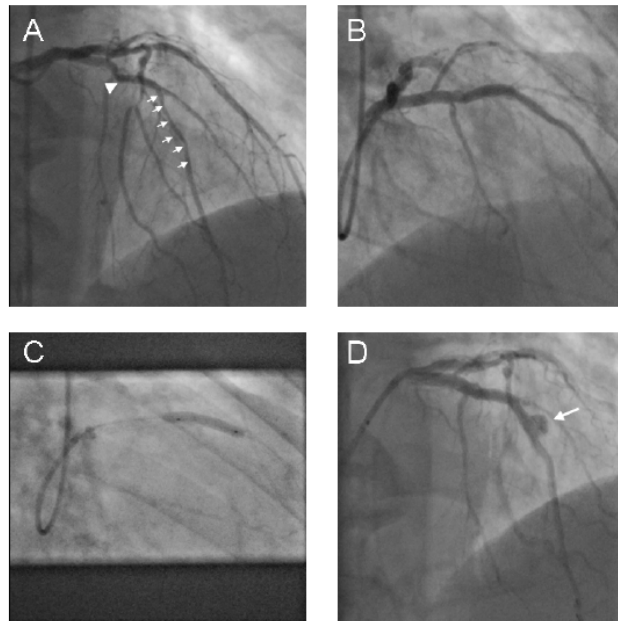
There are several reports of the use of PTFE-covered stents to seal coronary perforations with good effect.^{8–11}

However, these are widely acknowledged to be bulky devices that lack flexibility, and rapid deployment in calcified or tortuous vessels can be difficult, particularly in emergency situations. Furthermore, difficulties in achieving adequate stent expansion and the prospect of delayed re-endothelialization have led to concern about the increased potential for stent thrombosis or restenosis.⁹

We present the first report of the use of a novel highly deliverable pericardial covered stent to treat an iatrogenic coronary perforation during PCI, with angiographic follow up.

Case Presentation. A 74-year-old male with Canadian Cardiovascular Society Class 3 stable angina was admitted for elective staged PCI to the left anterior descending (LAD) artery. He was known to have three-vessel coronary disease, and had elected to undergo staged multivessel PCI rather than bypass surgery due to morbid obesity. He underwent successful PCI to the right coronary artery (RCA) 4 weeks previously and returned for PCI to the LAD, which had a severe lesion in the angulated proximal vessel and a long segment of diffuse disease beyond this (Figure 1A).

The procedure was performed via the right radial artery using a 6 French (Fr) Z2 EBU 3.5 guiding catheter (Medtronic, Inc., Minneapolis, Minnesota). Ten thousand units of heparin (weight-adjusted at 70 U/kg) was given at the beginning of the procedure with a further 4,000 units after 30 minutes to keep the activated clotting time (ACT) > 250 seconds. A BMW wire (Abbott Vascular, Abbott Park, Illinois) was passed down the LAD and the proximal and mid-vessel were predilated with a 2.5 x 20 mm Maverick balloon (Boston Scientific Corp., Natick, Massachusetts). Three Endeavor drug-eluting stents (Medtronic) were then deployed in an overlapping fashion (from distal to proximal): 2.75 x 18 mm, 3.5 x 30 mm, and 3.5 x 15 mm (Figure 1B). Postdilatation was then performed at the overlap of the middle and distal stents (Figure 1C) with a 3.5 x 20 mm Mercury NC non-compliant balloon (Abbott Vascular) at high pressure (20 atmospheres [atm]), resulting in an Ellis Class II perforation with localized extravasation of contrast (Figure 1D).



This was accompanied by severe chest pain and nausea. A 3.0 x 20 Maverick balloon was rapidly delivered to the perforation site and inflated at 8 atm in an attempt to seal the leak, but despite prolonged and repeated inflations, this was unsuccessful. Prolonged balloon inflations beyond 60 seconds were associated with chest pain and anterior ST-segment depression on the electrocardiogram (ECG).

Deployment of a Jostent Graftmaster PTFE-covered stent (Abbott Vascular) was considered, but not performed, as the operator did not feel this would track easily through the long stented segment and angulation in the proximal/mid-LAD, and the concern was that this could get stuck proximally with the inability to retrieve the stent and re-establish balloon tamponade.

Finally a 3.0 x 18 Over and Under® equine pericardium-covered stent (ITGI Medical Ltd., Or Akiva, Israel) was prepared and this was easily delivered and deployed at 14 atm, completely sealing the perforation with no residual leak (Figure 1E). ACT measurement post procedure was 222 seconds and heparin reversal was not performed. Echocardiography showed no evidence of a significant pericardial effusion or tamponade, and no CK rise was recorded. The patient was discharged the following day and was re-admitted electively 6 weeks later for staged PCI to the circumflex artery. Repeat angiography at this time showed widely patent LAD stents, with no evidence of restenosis (Figure 1F).



Figure 1. (A) Severe lesion and angulation of proximal left anterior descending (LAD) (arrowhead) and diffuse mid-LAD disease (arrows). (B) Post-deployment of three Endeavor stents. (C) Inflation of 3.5 x 20 mm non-compliant balloon at overlap of mid and distal stents. (D) Perforation at site of post-dilatation (arrowhead). (E) Postdeployment of 3.0 x 18 mm pericardium-covered stent, sealing perforation (inset: magnified view of perforation site). (F) Follow-up angiogram at 6 weeks showing patent stents.

Discussion. Although coronary perforation is infrequent, it is not rare, and it can be associated with significant morbidity and mortality. Furthermore, perforation rates can be markedly higher when adjunctive devices such as cutting balloons, laser and rotational atherectomy are used.^{1,6,7} The angiographic classification of perforation developed by Ellis et al is shown in Table 1.

Table 1. Angiographic classification of coronary artery perforation.

Classification	Description
I	Focal extra-luminal crater without extravasation limited to medial or adventitia
II	Pericardial or myocardial blush without contrast in pericardium; limited extravasation producing patch of blushing or staining within the myocardium or pericardium
III	Persistent extravasation with streaming or jet of contrast
IIIA	Directed toward pericardium
IIIB	Directed toward myocardium (e.g., ventricular cavity)

Modified from Ellis et al⁶ and Liu et al⁴

Class I perforations can be treated with prolonged balloon inflation and reversal of heparin, and are associated with a very low incidence of myocardial infarction or death. Class II and III perforations can result in cardiac tamponade with hemodynamic collapse (17–24% of patients),^{6,12} non-fatal infarction and death. Administration of Glycoprotein (GP) IIb/IIIa inhibitors may complicate matters, and when procedures are performed with bivalirudin (as is increasingly common), reversal of anticoagulation with protamine is not an option.

The PTFE-covered Jostent Graftmaster (Abbott Vascular) has been successfully used to seal coronary perforations and can be a lifesaving device.^{8–11} It consists of a balloon-expandable layer of PTFE sandwiched between two stainless steel stents. This makes the device bulky and relatively inflexible and limits its deliverability in calcified or tortuous vessels.^{9,10} High pressures and intravascular ultrasound (IVUS) guidance may be required to achieve adequate expansion. It may also be more prone to restenosis or thrombosis due to the effect of multiple layers of metal and synthetic PTFE material.

The Over and Under is a highly flexible laser-cut single stainless steel stent that is covered with processed biocompatible equine pericardium. The device is CE-marked and has only recently become available. The tissue is treated with a glutaraldehyde process which cross-links the collagen fibers and minimizes antigenicity, and is attached to the stent with polypropylene suture (Figure 2).



Figure 2. Over and Under[®] pericardium-covered stent.

The stent assembly is mounted on a specially designed balloon catheter; diameters of 3.0, 3.5 and 4.0 mm are available in stent lengths of 13, 18, 23 and 27 mm. Stent preparation involves two wash cycles of 2 minutes' duration with normal saline to remove the glutaraldehyde and thus cannot be used immediately upon removal of the packaging. However, even in the context of a perforation requiring prompt treatment, this delay is rarely detrimental, as the stent can be prepared during periods of balloon tamponade (as in this case). The avoidance of a "sandwich" configuration markedly enhances flexibility in angulated or tortuous vessels, and delivery of a 3.0 x 18 mm stent was easily accomplished through a 6 Fr guiding catheter through a long stented section of the LAD with marked angulation, and good expansion was achieved at moderate inflation pressures. Testing of the Over and Under stent in both phantom and porcine coronary models (Figure 3, courtesy of Dr. Haim Danenberg, Hadassah Hospital, Jerusalem, Israel) has shown superior deliverability over PTFE-stents by 19 ± 13 mm and 12 ± 10 mm, respectively ($p < 0.05$ for both models).¹³

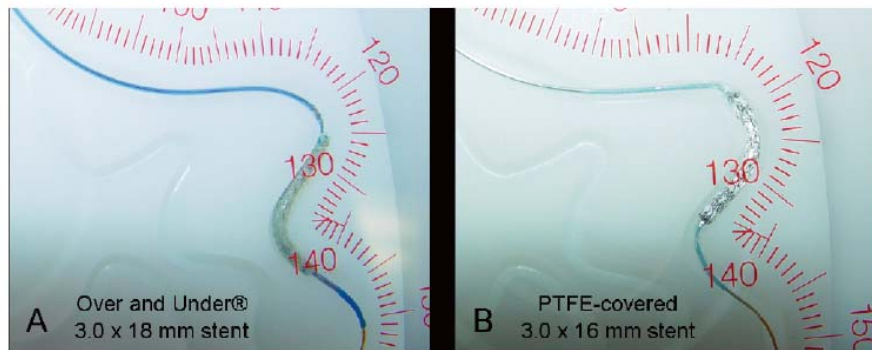


Figure 3. Comparison of deliverability of Over and Under® stent (A) with PTFE-covered stent (B) in phantom model, showing improved tracking of pericardium covered stent (courtesy of Dr. Haim Danenberg, Hadassah Hospital, Jerusalem, Israel).

In this case, therapeutic options were limited. It is unlikely that continued balloon inflation alone would have succeeded in this case, as repeated inflations had already failed to seal the leak while causing ischemic symptoms and ECG changes. Furthermore, the non-covered stent was likely to be splinting the vessel, preventing vasoconstriction. Reversal of heparin was considered, but this carries a risk of thrombotic complications, particularly if continued balloon tamponade is required. Finally, operative treatment was not an option, as our center does not have on-site surgery. The stent was widely patent at follow-up angiography 6 weeks later, and the patient experienced no adverse clinical sequelae, remaining well out to 6 months. Post-procedural dual antiplatelet therapy is recommended for 3 months, but will be continued in this case for 12 months, as drug-eluting stents were used (as per current guidelines). As the range of available equipment and operator expertise evolves, more complex anatomy is treated percutaneously. As calcified, tortuous and occluded vessels are increasingly tackled, the risk of vessel perforation remains, and interventional cardiologists require tools to deal with this complication. The Over and Under pericardium-covered stent is a valuable device in emergency situations for treating iatrogenic coronary perforation.

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The authors report no conflicts of interest regarding the content herein.

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