Case Reports

The Use of Membrane-Covered Stent Grafts in Thrombus-Containing Coronary Vessel Lesions

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Key words:
Percutaneous coronary angioplasty, stent grafts, complex coronary lesions, thrombus.

We describe two cases of severely symptomatic patients with coronary artery disease, who were treated by percutaneous transluminal angioplasty (PTCA) and direct deployment of synthetic membrane-covered stents (stent grafts) in highly thrombotic lesions. The first patient was a 67-year-old male with unstable angina eight years after bypass graft surgery and a thrombus-containing lesion in the body of the saphenous vein graft to the left anterior descending artery. The lesion of the vein graft was treated successfully with direct implantation of a stent graft 16 mm in length, without any sign of distal embolisation. The second patient was a 45-year-old male with a history of inferior myocardial infarction a month previously and three-vessel disease. During crossing of the right coronary artery (RCA) lesions with a wire, after successful PTCA of the left anterior descending and left circumflex arteries, a large thrombus appeared on the surface of the mid RCA segment lesion. A stent graft 19 mm in length was deployed without predilatation on the thrombus-containing lesion, resulting in entrapment of thrombi between the surface of the stent membrane and arterial wall with no impairment of the distal flow. Both of the patients were treated with long-term antiplatelet medication and remained asymptomatic, while coronary angiography six months after the procedures revealed no stent restenosis in any of the treated lesions. The technical issues of stent graft implantation and percutaneous coronary intervention strategy in the setting of endoluminal thrombosis are discussed, along with a review of the relevant literature.

Manuscript received:
July 24, 2003;
Accepted:
March 9, 2004.

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Intracoronary thrombus is a common finding on coronary angiograms from patients with acute coronary syndromes,[1-3] complex coronary lesions and degenerated venous grafts.[4] Percutaneous transluminal coronary angiography (PTCA) in thrombus-containing lesions, even when sufficient antiplatelet and antithrombotic medication is provided prior to the procedure, is associated with an increased incidence of peri-procedural myocardial infarction and ischaemic episodes, because of the increased likelihood of endoluminal thrombosis, peripheral embolism and the slow flow or "no-reflow" phenomenon.[5-9] The local genesis of endoluminal thrombus or the increase in quantity of pre-existing thrombus and its peripheral dispersal are one of the frequent causes of failure of the procedure. Platelet glycoprotein (GP) IIb/IIIa inhibitors, which have recently been used to treat high-risk patients, appear to reduce the unfavourable outcomes and thrombotic complications during PTCA, but do not solve the problem of thrombus detachment and peripheral embolism. The use of a commercially available membrane-coated stent graft (JO stent graft, JOMED GmbH, Germany), which consists of a distensible polytetrafluoroethylene (PTFE) membrane placed between two metallic stent struts, could reduce the risk of peripheral embolism during PTCA of thrombus-containing lesions, trapping

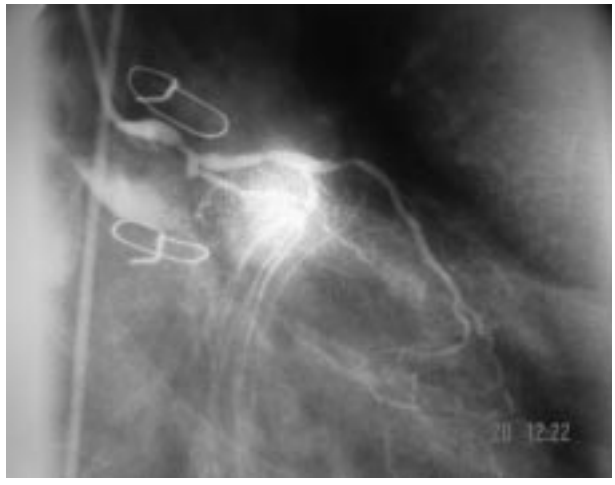

Figure 1. Patient 1. Angiogram of the left coronary artery showing 70% stenosis of the main branch and occlusion of the anterior descending artery after the origin of the diagonal branch.

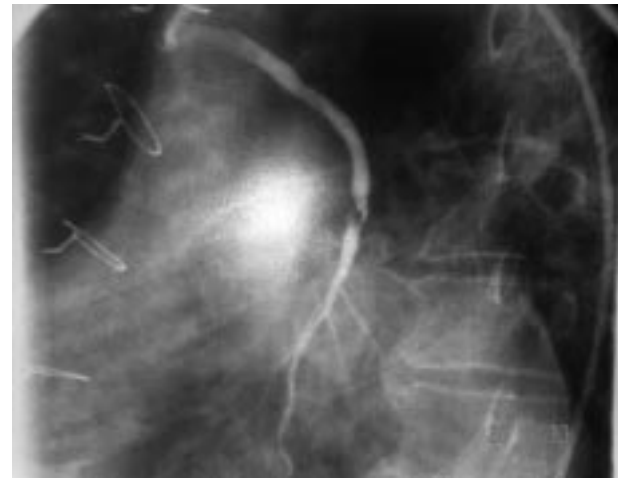

Figure 2. Outlined 90% stenosis with thrombotic material (filling defect) in the body of a saphenous vein graft in the anterior descending artery prior to the procedure (patient 1).

the thrombus between the surface of the stent membrane and the arterial wall.

We describe two cases of successful treatment of complex, thrombus-containing coronary lesions with the direct deployment (before balloon inflation) of stent grafts of this type.

Case report

First patient: A man aged 67 years with drug-refractory unstable angina was referred to our department for invasive treatment. He had a history of anterior myocardial infarction 8 years previously, following which he underwent coronary artery bypass surgery with implantation of a venous graft. He also suffered from arterial hypertension, hyperlipidaemia and diabetes mellitus. Angiography revealed mild left ventricular systolic dysfunction (ejection fraction, EF≈50%) and 3-vessel disease. The main branch of the left coronary artery had a 70% stenosis in the distal section, while the anterior descending branch showed occlusion peripherally to the origin of the 1st. diagonal branch (Figure 1). The right coronary artery had an occlusion in its proximal section, with its distal part being supplied by an anastomotic branch of the same artery, and the circumflex was occluded after the origin of the 1st. marginal branch, with filling of the 2nd. marginal branch via an anastomotic branch of the 1st. diagonal. An outlined 90% stenosis with a filling defect on its surface (thrombus) was identified in the body of the venous graft to the anterior descending artery (Figure 2). The decision was taken to treat the lesions in the venous graft and the main branch using PTCA and a loading dose was given of 300 mg clopidogrel per os, 5,000 IU heparin i.v. and eptifibatide (Integrillin, Schering-Plough) under the ESPRIT[10] protocol. The origin of the venous graft was catheterised with a preconfigured 7F right guiding catheter (right Judkins 4) and the lesion was approached using a medium stiffness 0.014″ guidewire. A free (not premounted on a balloon) stent graft (JO stent graft, JOMED GmbH, Rangendingen, Germany) 16 mm in length was placed by hand on a semi-compliant catheter-balloon 3.5 mm in diameter and 20 mm in length (Adante, Boston Scientific, Ireland), was advanced to the region of the lesion and implanted directly with a high-pressure balloon inflation (16 Atm). The result was complete opening of the stenosis with restoration of a smooth lumen in the venous graft, without residual stenosis, no sign of residual endoluminal thrombus and full preservation of peripheral coronary flow (Figure 3). The stenosis in the main branch was treated successfully, also with direct (no predilatation) placement of the stent graft. The patient's in-hospital course was uncomplicated and he showed no increase in cardiac enzymes on successive measurements. The patient returned home after 2 days, and remained under treatment with aspirin, nitrates, b-blockers and clopidogrel for the next 6 months. Six months later he remains symptom-free, with normal bodily activity, and without signs or symptoms of is-

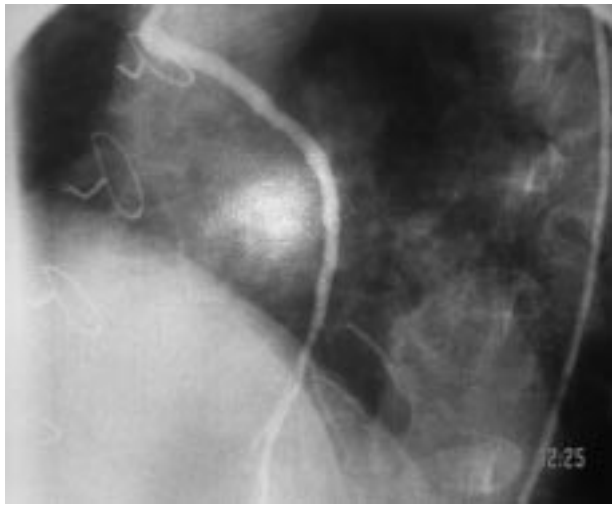

Figure 3. The final result of stent graft implantation in a thrombotic lesion of a venous graft, with excellent imaging of the distal vessels following the procedure. There is no residual thrombus or evidence of embolism.

chaemia on stress testing. Repeat angiography at 6 months showed absence of any restenosis of the lesion in the main branch and a widely patent venous graft without hyperplastic tissue within the implanted stent graft (Figures 4, 5).

Second patient: A man aged 45 years with a history of inferior myocardial infarction about a month previously and severe post-infarction angina was referred for invasive treatment. Diagnostic angiography showed a <50% lesion and a severe eccentric 75% stenosis in the proximal part and the 1st. third, respectively, of the anterior descending branch. The circumflex artery had severe disease, with a 90% eccentric lesion in its proximal section. The right coronary artery was predominant, with a wide lumen, and showed a 50-60% eccentric stenosis in its middle third, with another 70-80% stenosis peripheral to the posterolateral branch (Figure 6). Left ventricular function was preserved, with slight hypokinesis of the inferior wall. Following administration of a loading dose of 300 mg clopidogrel per os and 70 IU/kg heparin i.v., all lesions were treated with PTCA. A preformed 7F guiding catheter (left Judkins 4) was placed in the main branch of the left coronary artery and the critical stenoses in the anterior descending and circumflex arteries were opened via direct placement (no balloon predilatation) of conventional stents. A 7F guiding catheter (right Judkins 4) was placed in the right coronary artery and the two successive lesions were approached with a medium stiffness 0.014″ guidewire without difficulty. A new, large filling defect (thrombus) immediately appeared on the surface of the stenosis in the middle third (Figure 7). Within a short time the coronary flow showed severe deterioration (TIMI flow I), while a reduction in flow towards the posterolateral branch of the right coronary artery was also observed, with a greatly attenuated angiographic image in both cases (Figure 8). At this stage, the patient complained of intense chest pain and showed exaggerated ST-T segment el-

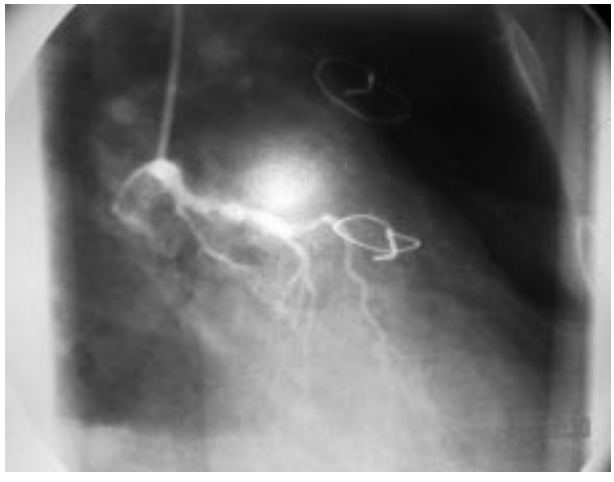

Figure 4. Repeat angiogram at 6 months showing a conventional stent in the main branch with no restenosis (patient 1).

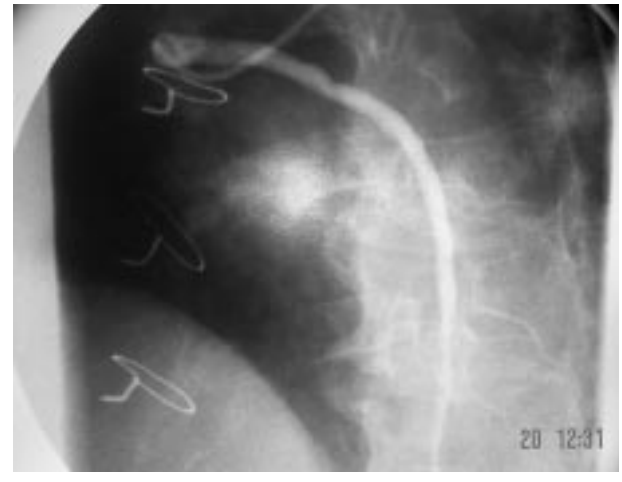

Figure 5. Patient 1. Repeat angiogram at 6 months showing the stent graft in the venous graft with no restenosis.

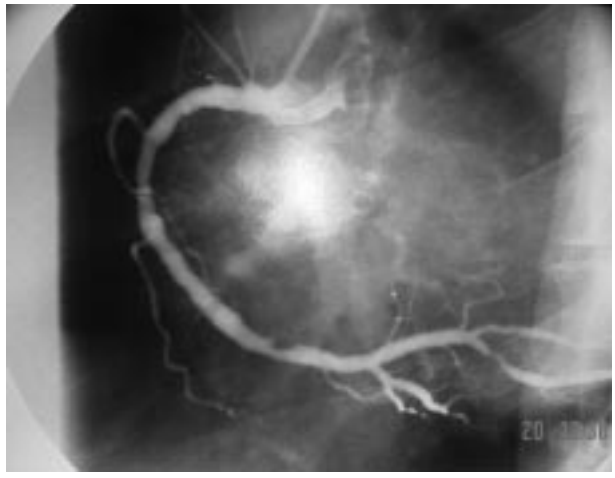

Figure 6. Angiogram showing the right coronary artery in patient 2 before the procedure. Two lesions may be seen: one non-critical, eccentric, in the middle section, and one critical stenosis, peripheral, in the posterolateral branch.

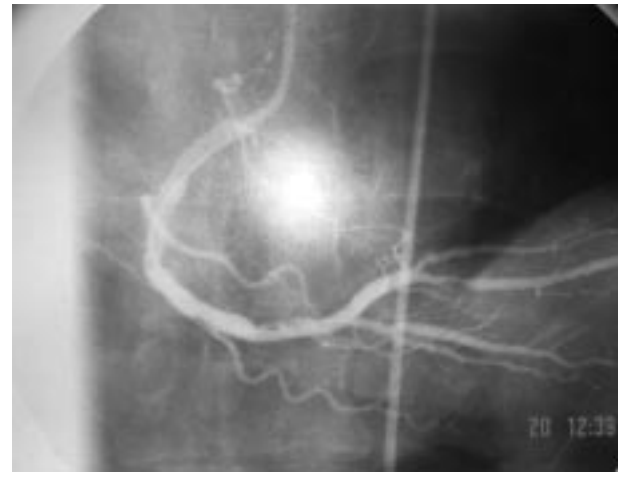

Figure 7. After placement of the guidewire a large quantity of surface thrombus (filling defect) appears in the lesion in the middle third.

evation on the inferior and lateral surface ECG leads. An appropriate dose of abciximab (Reopro, Elli Lilly) was immediately given i.v. and a free stent graft (JO stent graft, JOMED GmbH, Rangendingen, Germany) 19 mm in length was placed on a semi-compliant catheter-balloon 4.0 mm in diameter and 20 mm in length (Adante, Boston Scientific, Ireland) and advanced to the site of the lesion. The stent was implanted directly (without predilatation) and successfully following high-pressure balloon inflation. The result was a wide open arterial lumen with no signs of residual thrombus or peripheral embolism. After the restoration of flow towards the periphery of the vessel the patient's ECG became physiological and the pain receded. The procedure was completed with another direct implantation of a conventional stent in the peripheral lesion of the right coronary artery, after it had been advanced to the stenosis through the more proximally implanted stent graft (Figure 9). The patient's in-hospital course was un-

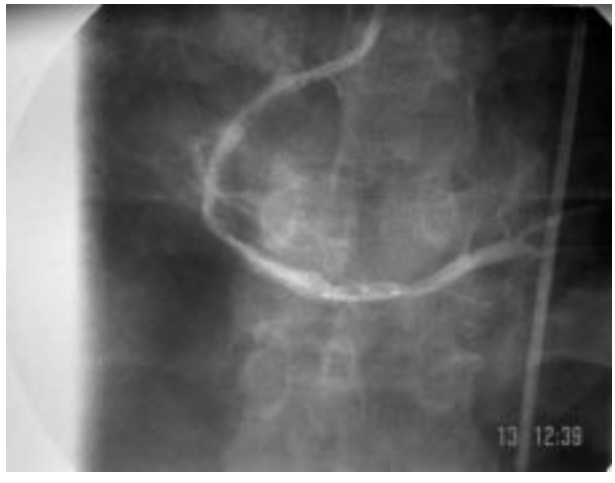

Figure 8. Extensive thrombosis of the right coronary artery in the region of the lesion, with disturbances of coronary flow and no imaging of the distal branches.

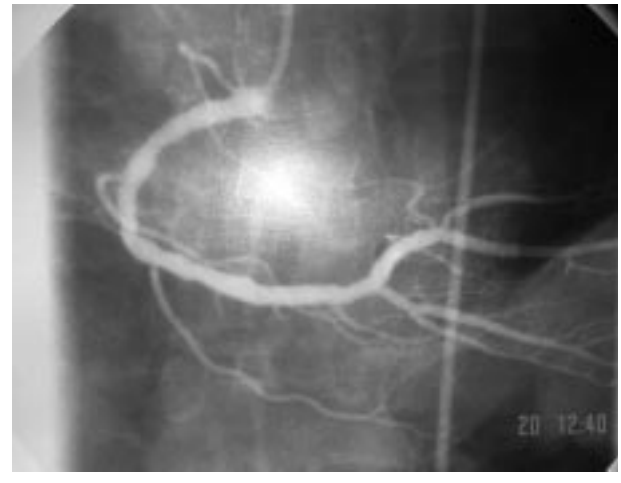

Figure 9. Final result of PTCA in the right coronary artery following the direct implantation of a stent graft in the thrombotic lesion of the middle section and a conventional stent in the lesion of the distal section. There is no residual thrombosis. Full restoration of distal coronary flow, without embolism.

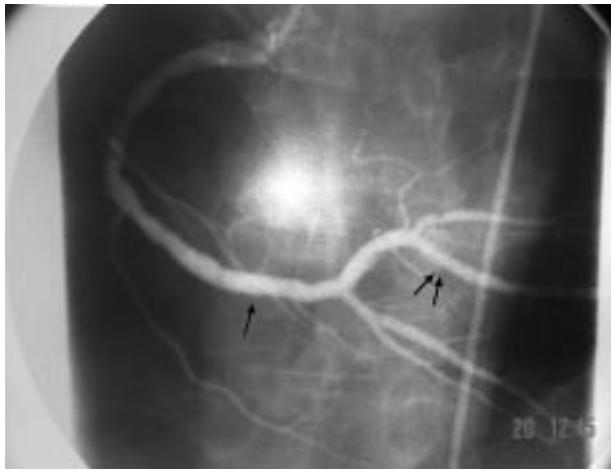

Figure 10. Repeat angiogram at 6 months in patient 2. The stent graft in the middle third of the right coronary artery (single arrow) can be seen to be patent and free of restenosis. The conventional stent in the posterolateral branch (double arrow) is also patent.

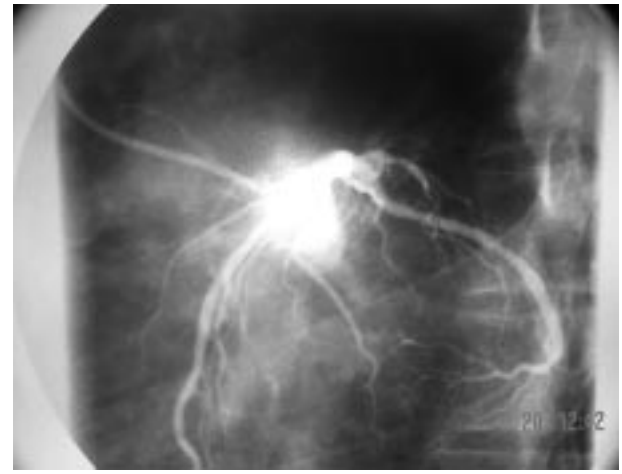

Figure 11. Patient 2. Patent conventional stent in the circumflex artery on repeat angiogram at 6 months.

complicated, with normal successive cardiac enzyme levels. He returned home two days later, under treatment with aspirin, diltiazem and a six-month course of clopidogrel. Ten months later he remains symptom-free, without signs of ischaemia on stress testing, while a repeat angiogram showed that the stented sections were widely patent, without evidence of intra-stent restenosis, either in the stent graft or in the conventional stents (Figures 10-12).

Discussion

The existence of intracoronary thrombus is related with an increased incidence of complications during PTCA and is one of the most difficult circumstances the interventional cardiologist has to face. The occurrence of peri-procedural myocardial infarction, especially of large extent, is connected with a worse long-term prognosis for the patient and is a complication most often reported during procedures involving lesions in venous grafts. This was shown by Hong et al,[11] who studied 1,056 consecutive patients with angiographically successful PTCA for 1,693 venous graft lesions. The first-year mortality was significantly higher in patients who exhibited a peri-procedural increase in CK-MB levels, even in those who had no apparent in-hospital complication. A massive peripheral embolus from thrombotic or other friable material during PTCA may occlude large epicardial vessels, but the biggest problem is microvascular occlusion by small-sized particles (15-100 microns), which leads to microinfarcts in the myocardium and to left ventricular dysfunction. The concomitant development of spasm and endothelial dysfunction from the local release of vasoactive substances places a further strain on myocardial function. Limited success in the treatment of the "no reflow" phenomenon has been reported with the administration of calcium channel

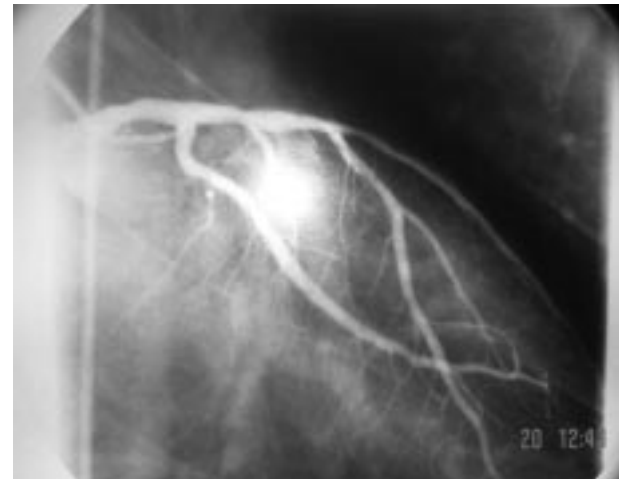

Figure 12. Repeat angiogram in patient 2, showing a patent conventional stent, free of restenosis, in the middle third of the anterior descending artery, while the moderate stenosis in the proximal section remains unchanged.

inhibitors, adenosine, adrenaline and sodium nitroprusside.[12] Intensive drug therapy and techniques designed to avoid the detachment of a thrombus or to trap it and remove it from the circulation have been used to improve the results of angioplasty for complex thrombotic lesions. Patients with acute coronary syndromes take platelet GP IIb/IIIa inhibitors prior to or during the procedure, while the long-term administration of intravenous urokinase in thrombus-containing stenoses has also been suggested.[13,14] Local administration of intracoronary urokinase during angioplasty, via special coronary catheter systems for drug delivery, has been used in PTCA for high-risk coronary lesions.[15-17] Recently, the local, intracoronary administration of abciximab prior to angioplasty was found to be effective and was related with fewer peri-procedural complications in similar lesions.[18] Transluminal extraction coronary atherectomy has also been used for the percutaneous treatment of thrombotic lesions in degenerate or thrombotic old venous grafts, with improved success but with the appearance of a persistent and non-reversible "no reflow" phenomenon in most cases.[19] There are recent reports of the successful use of special devices, known as peripheral protection devices, that allow the trapping and collection of embolising particles during coronary procedures. The greatest international experience has been reported with regard to the PercuSurge Guardwire™ system (Boston Scientific, Boston Massachusetts, USA), while newer devices, such as Angioguard™ (Cordis, USA), Medtronic AVE Distal Protection Device™ (DPD Medtronic AVE, Santa Rosa CA, USA) and FilterWire EX™ (Boston Scientific/EPI, Boston Massachusetts, USA), are still under clinical evaluation. Donald Baim, on behalf of the researchers in the SAFER study,[20] reported significantly fewer major adverse coronary events (MACE) (8.8% vs. 17.3%), particularly the incidence of acute myocardial infarction (Q and non-Q) and the "no reflow" syndrome, during PTCA of venous grafts using the PercuSurge Guardwire™. Other researchers have reported similarly improved results (MACE 5.7% to 7%) from using various peripheral protection devices.[21-23] Techniques for the transluminal absorption of thrombotic material from complex lesions of native coronary arteries or venous grafts have been used recently prior to angioplasty, with a view to shrinking the volume of the thrombus and reducing the immediate complications of the endoluminal procedure. Rheolytic thrombectomy with the POSSIS AngioJet™ system is based on hydrodynamic principles and uses a double-lumen catheter to break up a non-organised thrombus in a coronary vessel and siphon it into a special collecting case outside the circulation.[24,25] In comparison with urokinase administration, in the VeGAS 2 randomised study, this method showed greater angiographic success and improved efficacy, with a lower incidence of major cardiac events during the first 30 days' follow up.[25] Intracoronary thrombectomy with the X-Sizer™ catheter system is a similar technique for breaking up, mobilising and removing thrombotic or other soft material from the coronary circulation. Its use in invasive coronary angioplasty in patients with a large quantity of endoluminal thrombus was accompanied by a high success rate and few immediate complications.[26] Recently, Beran et al[27] published the findings from the use of the device prior to angioplasty in patients with acute coronary syndrome and reported better epicardial coronary flow and faster disappearance of ST-T changes on the ECG, compared to a control group.

A possible alternative technique in high-risk patients is the implantation of a stent that is able to trap the thrombus locally and prevent its detachment and peripheral embolism during coronary interventions.

Theoretically, the direct (without balloon predilatation) placement of endoluminal stents should reduce the risk of detachment of fragile material from the surface of the arterial stenosis during PTCA. This idea is supported by reports showing that angioplasty in old, degenerate venous grafts with direct stent placement is correlated with fewer occurrences of peripheral embolism or "no reflow" phenomenon.[28] In spite of this, the peri-procedural complication rate remains higher in PTCA performed on a thrombotic substrate.[29] Stents covered with a biological membrane (stent grafts) have the ability to isolate the vascular wall from the lumen, and the first autologous or heterologous vein-covered stents have been used mainly to repair ruptures of the vessel wall that may be caused as a complication of percutaneous procedures, or for the transluminal repair of coronary aneurysms.[30-35] They have also been used in stenotic lesions of saphenous vein grafts with good acute and long-term results.[36] Recently, Stefanadis et al[37,38] described the use of autologous vein- or artery-covered stents in the percutaneous transluminal treatment of coronary disease, with very satisfactory immediate and long-term results. Their use, however, has been held back by the inherent limitations of the first generation of stent

grafts (surgical acquisition of autologous veins or arteries, large size of the resultant device and inflexibility of the stents). With the new generation of stent grafts, covered with a synthetic PTFE membrane and having a smaller profile, autologous vein or artery grafts no longer need to be obtained and the first clinical reports are quite optimistic.[39,40] So far, these devices are indicated and have been used for the management of complications in PTCA,[39-44] such as rupture of the coronary vessel, and for the percutaneous closure and repair of coronary artery aneurysms, either automatic or procedure-related.[40,45,46] The implantation of stent grafts in venous grafts used for coronary bypass, according to early reports, is also associated with a relatively low restenosis rate.[39,47] In another report, Baldus et al,[48] in a multicentre, nonrandomised study, examined the efficacy of membrane-coated stents in the treatment of lesions of venous bypass grafts, although they did not provide data concerning the incidence of thrombotic lesions in their study population. They reported a high success rate for implantation (99%) in 103 patients, in who 125 stent grafts were implanted, with grade 3 TIMI flow at the end of the procedure in 95% of lesions. After 6 months' follow up, repeat angiography showed obstructive restenosis of the stent in 8% and stent reocclusion in 9% of patients (total restenosis 17%), while 8% of the patients underwent target vessel revascularisation and 3% required a new bypass operation. The particularly favourable results of this study, however, should be viewed with a degree of scepticism, since it did not have a randomised design and the rather small patient sample does not allow firm conclusions to be drawn.

Recently, the results were published from two quite large, randomised studies that compared the effectiveness of implanting synthetic PTFE stent grafts, compared with conventional metal stents. Stankovic et al,[49] in the RECOVERS study, compared 156 patients who received PTFE stent grafts for venous graft stenosis with 145 patients having similar stenoses treated with conventional metallic stents. Thrombus was present in 10.8% of lesions in the stent graft group and in 6.4% in the conventional stent group, while the incidence of angiographically "degenerated" grafts was 40.9% and 32.7% for the two groups, respectively. The authors reported a significantly higher rate of MACE, in-hospital and at 30 days, in the stent graft patients (10.9% vs. 4.1%), which was due to the significantly greater incidence of myocardial infarction (non-Q in the great majority) in that group. In contrast, at 6-month follow up the MACE did not differ between the two groups (23.1% vs. 15.9%, respectively) and the incidence of angiographic restenosis of the lesions was similar (24.2% vs. 24.8%, respectively). The high rate of early MACE in the stent graft group might be attributable either to the technique employed (very high-pressure stent dilation causing damage to the extremities of the stent) or to the failure of the devices to prevent embolic complications.

In the similarly designed, randomised STING study, Schächinger et al[50] implanted stent grafts in 102 patients with venous graft disease and compared them with 104 patients receiving conventional stents. In both groups the complication rate was 28%, although the frequency of thrombus was not recorded and protection devices were only used in a small proportion of cases in both groups (8.8% and 9.6%, respectively). The researchers in this study did not find any differences between the two groups as regards the in-hospital course, the 30-day MACE or the long-term clinical course over 15 months' follow up. These results do not indicate any superiority of stent grafts for the prevention of peripheral embolism, while the rate of angiographic restenosis was slightly (not statistically significantly) higher in the group of patients receiving PTFE stent grafts (29% vs. 20%).

In the RECOVERS and STING studies, the existence of complex lesions, most probably similar to those in our patients, was reported in around a third of the cases and administration of theienopyridine agents was continued for only 3 months, in contrast to our patients, who received clopidogrel for 6 months following the procedure. It is characteristic that both these newer studies reported a smaller initial success rate for the procedure (87% in both), no difference in the appearance of the "no reflow" phenomenon and a higher long-term restenosis rate than that reported by Baldus et al,[48] while the long-term occlusion rate in PTFE stents was 9% and 13%, respectively. These findings, along with the particular type of restenosis reported by the authors for this prosthesis, mainly at the extremities of the stent graft,[39,49,50] underline the need for further studies of specific types of complex coronary lesions, and especially those containing thrombus, since it appears that stent grafts are not in general superior to conventional metallic stents when implanted in coronary bypass grafts. The results of the American BARRICADE study, currently in progress, are awaited with great interest and may clarify the questions that now exist. It is possible

that the ability of stent grafts to trap an endoluminal thrombus on the wall of the vessel may contribute significantly to a reduction of risk and an increase in the effectiveness of percutaneous coronary procedures in cases with a thrombotic substrate.

In this report we have described the first cases in Greece of the direct implantation of PTFE stent grafts in complex, thrombus-containing lesions of the coronary vessels. In both cases the angiographic and clinical results of the procedure were excellent, in spite of the presence of large quantities of endoluminal thrombus. The use of stent grafts allowed the percutaneous procedure to be completed in one stage, without the need for prolonged administration of intravenous heparin or intracoronary thrombolytic drugs, while no post-procedural complications were observed. In our department the method has already been applied, so far with 100% success, in a selected group of 19 patients with complex coronary artery lesions and angiographically visible thrombus. The long-term results from this group await the completion of the follow up period.

This method contributes to solving the problems of coronary procedures involving thrombus-containing lesions, since it combines the advantages of direct stent implantation (avoiding detachment of thrombus and friable material) with those of stent grafts (trapping the thrombus and confining it between the vessel wall and the stent membrane). Special care is needed in the selection of the correct size of stent, in order for the thrombotic lesion to be covered adequately along its length and for the stent to be fully apposed in contact with the vessel wall, after balloon inflation at quite high pressures, because of the increased rigidity and resistance inherent in its design.

In case of inadequate expansion, the stent must be re-expanded with a balloon of larger diameter and short length, so that the surface of the stent is in full contact with the vessel wall and traps the thrombus locally. In general, most researchers do not recommend –as in all stent implantations in venous grafts– expansion of the stent under very high pressures, apart from certain exceptions,[49] but rather expansion using a balloon of greater diameter and shorter length. The PTFE stent grafts that are commercially available, 12-19 mm in length, free or pre-mounted on balloons of various diameters, are less flexible than conventional stents and their placement may present difficulties in angulated arteries or in peripheral sections of the coronary net. It is recommended that the guiding catheter chosen should have the maximum possible support, as well as the use of a relatively stiff guidewire with intermediate or extra support in all cases. In our patients, the lesions were located in relatively straight sections of the vessels, a fact that facilitated stent placement using a guidewire of medium stiffness. The successful implantation of stent grafts in selected high-risk and unstable patients with large quantities of endoluminal thrombus may be a life-saver (as in case 2) and converts a complex intervention (need for prolonged presence of sheaths in the arteries, administration of intracoronary thrombolysis, high peri-procedural complication rate) into a much simpler procedure. The main concerns regarding the use of stent grafts are: their high profile and consequent reduced manoeuvrability in comparison with conventional stents; the fact that they cannot be implanted in lesions close to the origin of a large lateral branch of critical importance for myocardial perfusion; their restenosis rate, which still has not been determined from large studies; and the increased likelihood of acute or late thrombosis that has been reported by some investigators.[50,51] These problems may be avoided if the devices are used in relatively large arteries, expanded as fully as possible in order to achieve an excellent result, and combined with administration of antiplatelet drugs for a long period following the procedure. In this way, the apparent slow growth of endothelium over the interior surface of the stent is facilitated[50,52] and late thrombotic events may be avoided. The profile of these stents should be lower in third generation devices.

In conclusion, the direct implantation of PTFE stent grafts in complex, thrombotic, coronary artery lesions in selected patients is possible and can prevent peripheral embolism, reducing the risk of periprocedural complications during PTCA in these patients.

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