JACC Vol. 13, No. 5
April 1989:1085–91

Intravascular Stenting for Stenosis of Aortocoronary Venous Bypass Grafts

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To test the ability of endoluminal stents to prevent saphenous vein graft restenosis after balloon angioplasty, 13 patients with angina and previous coronary bypass surgery underwent implantation of one or more stents into 14 stenosed grafts. Implantation was technically successful in all cases and there were no major in-hospital complications. During a median follow-up interval of 7 months (range 2 to 26), 10 patients (77%) underwent follow-up angiography. Seven patients remained asymptomatic or in improved condition without further intervention; three patients had further angioplasty with stent implantation for a new stenosis in the same graft. Two patients (20%) developed within-stent restenosis. There was one death from progressive congestive heart failure 7 months after implantation. No patient had a myocardial infarction or needed surgical revascularization during the follow-up period.

In selected cases, stent implantation appears to be a promising new technique that may decrease the incidence of restenosis after balloon angioplasty in venous bypass grafts. The rate of complications is low. Further experience and longer follow-up will be needed before definite recommendations can be made about its use.

(J Am Coll Cardiol 1989;13:1085–91)

Recurrent angina due to graft attrition after coronary artery bypass surgery often constitutes a difficult therapeutic problem. Reoperation is associated with increased morbidity and mortality (1,2) and long-term results have been reported to be inferior to those of the first intervention (3). Balloon angioplasty is often an effective alternative to surgery in such a situation; it has a low rate of complications (4–6) and initial success rates vary from 80% to 96% depending on location of the lesion (6). However, the restenosis rate is high: 26% to 43% in the larger series (5–7) and even higher (61%) when the lesion is situated in the graft body rather than at the proximal or distal site of anastomosis (4–6).

Because of this well documented high restenosis rate, on the one hand, and the potential risks of a second surgical intervention, on the other, it appears desirable to improve the long-term results of balloon angioplasty. We report our initial experience with stent implantation after balloon angioplasty for stenosis and restenosis in saphenous bypass grafts.

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Manuscript received June 20, 1988; revised manuscript received November 2, 1988, accepted November 23, 1988.

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Methods

Study patients. Between April 1986 and May 1988, 13 patients underwent implantation of one or more stents into 14 saphenous vein bypass grafts. Ten patients had undergone one coronary bypass operation, and the remaining three had had two separate operations. The last surgical revascularization procedure had been done a median of 5 years earlier (range 1 to 16), with a median of three grafts per patient (range two to four). At the time of stenting, a median of two grafts (range one to three) were occluded or stenosed.

There were 11 men and 2 women with a mean age of 63 ± 7 years. All had stenosis of at least one coronary bypass graft, multivessel disease of native coronary arteries and anginal symptoms, either stable exercise-induced (12 patients) or unstable symptoms at rest (1 patient). Left ventricular ejection fraction was only moderately impaired for most patients (median 57%, range 40% to 68%). Five patients were treated for lesions that had recurred after previous balloon angioplasty (median of two previous angioplasty procedures, range one to four). Some of the data concerning the first three patients in this series have been previously reported (8). Although stent implantation was performed

0735-1097/89/$3.50

with surgery available on standby in all cases, two patients had a clear contraindication to elective coronary bypass reoperation (one with previous severe mediastinitis and one had no more veins available for grafting in either legs or arms); and seven patients had a relative contraindication to surgery (two previous bypass operations in three and poor general condition or associated disease in four).

The vein graft lesions. The target lesions were situated in a saphenous graft in all cases: three to the left anterior descending coronary artery, seven to the lateral circumflex coronary artery or a marginal branch and four to the right coronary artery. One lesion involved the proximal graft implantation site on the aorta and all others were situated in the body of the graft. Lesion severity was assessed from diameter reduction in at least two perpendicular angiographic views. Only lesions that reduced the mean luminal diameter by ≥70% were considered for treatment. Initial success was defined as the absence of any residual stenosis within the stented segment after implantation, and restenosis was defined as a diameter reduction of ≥50% within the stented segment at follow-up angiography.

Selection of patients. *Criteria for selection were* 1) anginal symptoms not controlled on medical therapy, 2) graft lesion technically amenable to balloon angioplasty (stenosis or restenosis), and 3) informed consent obtained.

Patients were excluded if 1) the bypass graft was occluded; 2) the angioplasty catheter failed to cross the lesion; 3) the lesion was considered unsuitable for stenting (i.e., there were important difference in diameter between the proximal and distal portion of the vessel segment to be stented, poor distal runoff, location of the lesion at the distal anastomosis with both anterograde and retrograde flow in the recipient coronary artery); and 4) informed consent was not obtained.

During the study period, five patients underwent vein graft balloon angioplasty but did not receive a stent. The reasons for not stenting the grafts were unsuitable anatomy in three cases, failed angioplasty (lesion not crossed with the balloon) in one case and angioplasty for an occluded graft in one case.

Stent. The stent (Medinvent), which has been described previously (8), is composed of a stainless steel alloy and has a self-expanding mesh design. It is flexible along its long axis; its length for coronary graft implants varies between 15 and 29 mm and its diameter in the fully expanded state is typically 3 to 6 mm. For any given lesion a stent is selected with a fully expanded diameter approximately 15% larger than the estimated normal lumen of the recipient graft so that it will be stable once positioned and exert a residual radial pressure on the vessel wall. Before implantation, a doubled-over membrane maintains the stent constrained and elongated on the delivery system. This is introduced into the coronary artery through a standard 8F or 9F guiding catheter over an exchange guide wire. Retraction of the membrane allows the stent to be progressively released into the vascular lumen (Fig. 1).

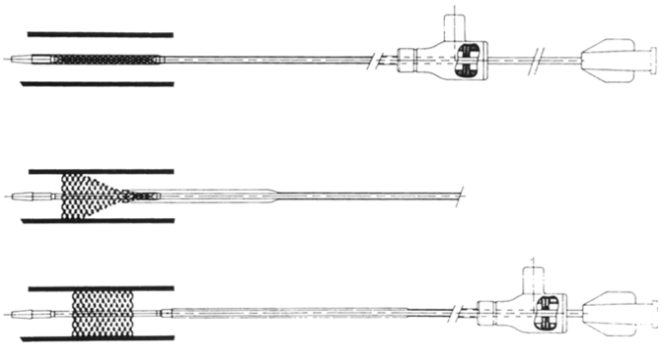

Figure 1. Diagram of stent implantation. **Top,** The stent is constrained and elongated on the delivery system. **Middle,** The doubled-over membrane has been inflated and partially retracted. The stent is half-released and its distal extremity is expanded. **Bottom,** The stent is completely released into the recipient vessel, the membrane is fully retracted and the introducing device is free to be retrieved.

Protocol. Angioplasty was performed according to current practice and all stents were implanted by the same operator as previously described (8). After intravenous administration of 10,000 to 15,000 IU of heparin and completion of balloon angioplasty, all patients received an additional 5,000 IU of heparin just before stent implantation; heparin infusion was continued without interruption after implantation until oral anticoagulation was effective. A low dose (up to 100,000 IU) infusion of urokinase was given through the guiding catheter during and immediately after the stent implantation. Oral anticoagulant administration, begun on the day of implantation, was continued for 3 months and dosage was adjusted to maintain an international normalised ratio for thromboplastin time (INR) of 2.3 or more. Also prescribed were nifedipine (30 to 60 mg/day), aspirin (100 mg/day) and dipyridamole (300 to 450 mg/day). In the last nine cases, sulfinpyrazone (400 to 800 mg/day) was added to this regimen.

Results

The stented graft stenoses were situated in the body of the graft in 13 cases and at its proximal implantation into the aorta in 1 case (Table 1). The median luminal diameter reduction was 90% (range 75% to 95%) and median stenosis length was 5 mm (range 4 to 17) before angioplasty. After one or more balloon inflations the median stenosis was reduced to 40% (range 5% to 90%).

Stent implantation. Implantation was successful in all 13 patients and the target segments could be covered in all cases with no appreciable residual stenosis (Fig. 2). During a single procedure, seven patients received one stent, four patients received two stents in the same graft, one patient

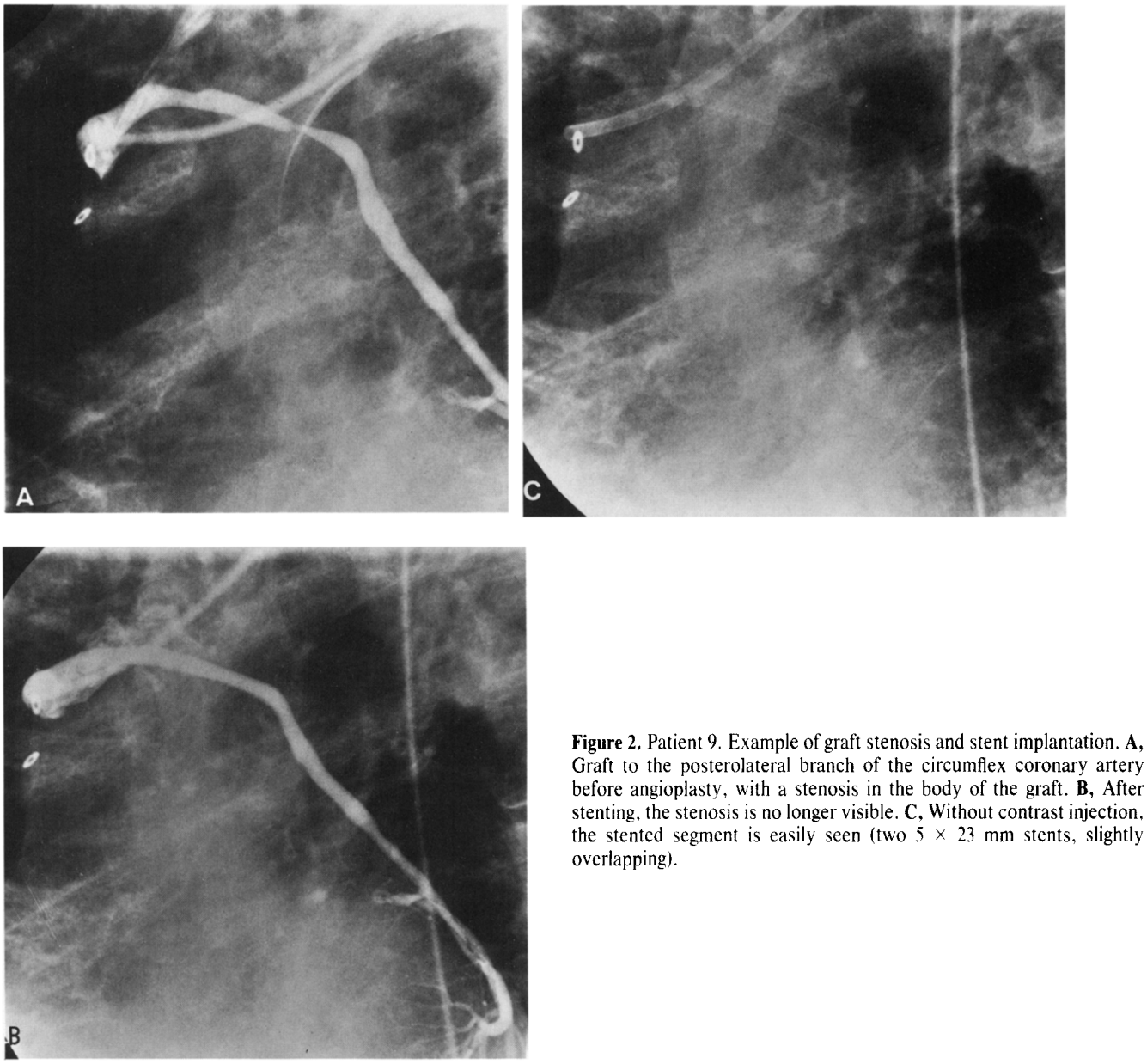

Figure 2. Patient 9. Example of graft stenosis and stent implantation. **A,** Graft to the posterolateral branch of the circumflex coronary artery before angioplasty, with a stenosis in the body of the graft. **B,** After stenting, the stenosis is no longer visible. **C,** Without contrast injection, the stented segment is easily seen (two 5 × 23 mm stents, slightly overlapping).

received two stents in different grafts and one patient received three stents in one graft. Placement of the stent was considered satisfactory for 19 (95%) of 20 devices. In one case (Patient 9) a second stent was necessary to completely cover the target area, because the first device was implanted somewhat proximally because of difficulties with the introducing device. Median stent diameter in the unconstrained state was 4 mm (range 3 to 6) and median length was 23 mm (range 15 to 29).

Ventricular fibrillation occurred during the procedure in one patient because of prolonged ischemia. Prompt return to sinus rhythm was achieved with direct current cardioversion with no long-term adverse effects. There was one case of distal coronary embolization after balloon angioplasty, before stent implantation. This led to transient occlusion of a retroventricular branch but was without clinical consequences.

In-hospital follow-up. The median hospital stay after implantation was 4 days (range 2 to 10). There were no cases of death, coronary bypass surgery or myocardial infarction. Serial creatine kinase levels remained within normal limits in all cases. One patient required blood transfusion because of bleeding from the femoral puncture site after the introducer was withdrawn and one patient underwent elective surgery for a femoral artery pseudoaneurysm 7 days after stent implantation.

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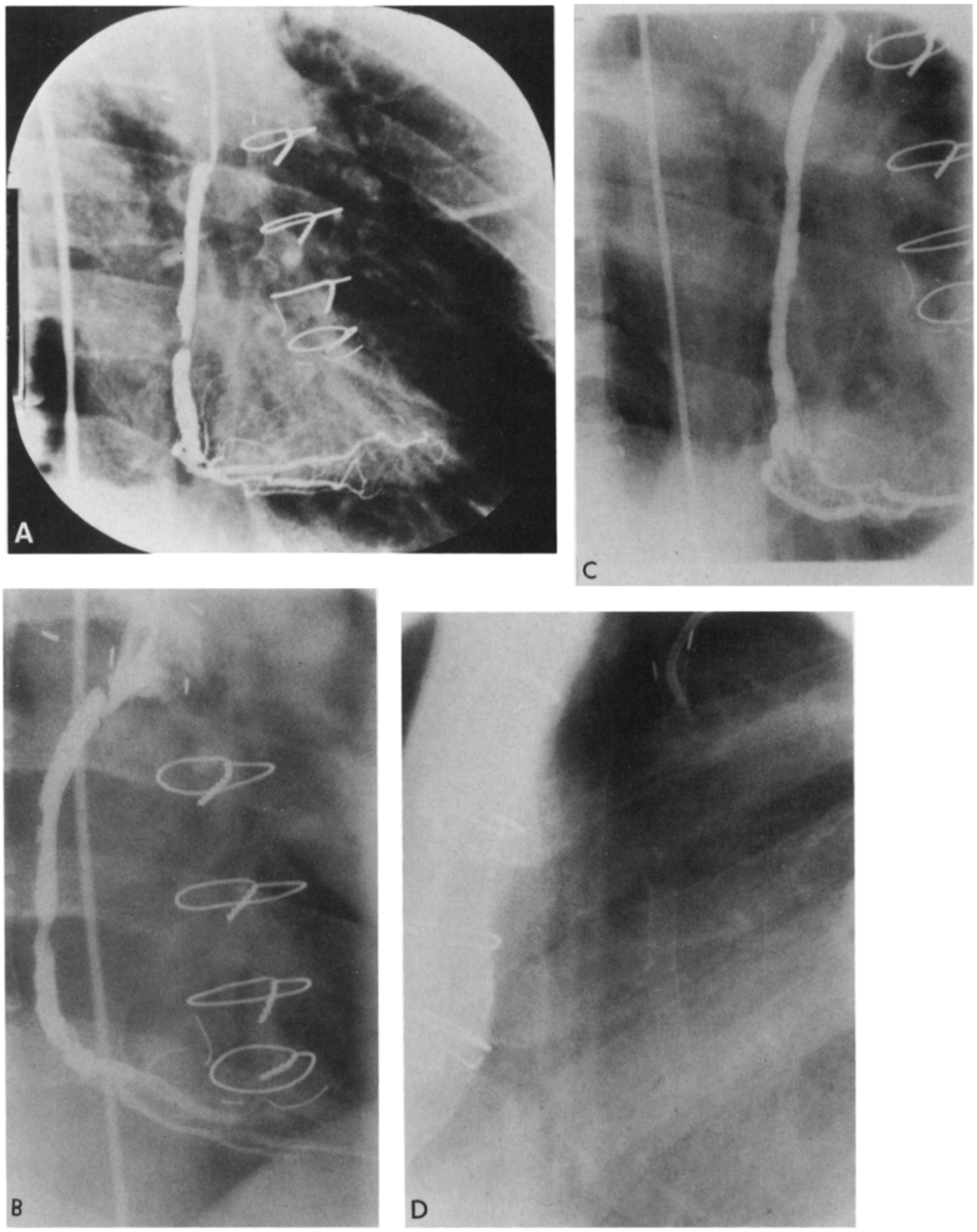

Figure 3. Patient 2. Example of a new stenosis developing proximal to an implanted stent. **A,** Tight stenosis in saphenous graft to the right coronary artery, before angioplasty and stent implantation. **B,** Same graft 11 months after the first stent implantation (4.5 × 20 mm). An eccentric new proximal lesion is visible, together with a moderate stenosis immediately proximal to the stent. **C,** Follow-up angiogram 15 months after implantation of two additional stents (each 5 × 22 mm). There are some irregularities both within and outside the stented segments, but no significant stenosis or restenosis. **D,** Same view as in C, without contrast injection. The three stents are easily seen.

Long-term follow-up. All patients were followed up clinically for a median of 7 months (range 2 to 26). During this period, seven patients remained asymptomatic or in improved condition without further intervention. Two patients required a second stenting procedure: the first for two new lesions in the same graft (one immediately proximal to the stent and another at some distance proximally from it [Fig. 3]), and the second for a single new lesion immediately proximal to the stented segment. One patient had two further stenting procedures, each time for a new stenosis that occurred immediately proximal to the previously implanted prosthesis. All three patients who required more than one stenting procedure were further followed up and shown to have a satisfactory clinical response 3, 4 and 15 months, respectively, after the last stent implant. Two of them have

undergone follow-up angiography 3 and 15 months after the last stent implantation; there was no restenosis or new stenosis of the graft.

One patient, aged 72 years, who had undergone coronary bypass surgery 16 years previously, died 7 months after stent implantation from progressive heart failure. No symptoms or signs suggesting acute occlusion of the stented graft had developed. He did not undergo follow-up angiography or necropsy.

Follow-up angiography. To date, 10 patients have undergone coronary angiography, a median of 5 months (range 3 to 26) after stent implantation. Significant restenosis (≥50% mean luminal diameter reduction) within the stented segment was observed in two patients (20%). One of them developed recurrent stenosis of both stented segments in two bypass grafts. One restenosis occurred together with marked progression of disease outside the stented segment and no further intervention was attempted at that site. The restenosis in the other graft was first treated by balloon angioplasty with a temporary improvement of symptoms. Because of recurrent symptomatic restenosis, percutaneous transluminal atherectomy (9) was then performed 6 months later within the stented segment with a good immediate result (Simpson, personal communication). The second patient with restenosis was treated by balloon angioplasty alone 4 months after stent implantation, with a good clinical and angiographic response (Jean Marco, MD, personal communication).

Three patients, all with disabling angina before stent implantation, did not undergo follow-up angiography. One of them died and two have remained asymptomatic. If it is assumed that the absence of angina corresponds to the absence of restenosis and that the patient who died may have had a recurrence in one or both stents, the restenosis rates would be: 3 (23%) of 13 patients, 4 (29%) of 14 grafts and 4 or 5 (20% to 25%) of 20 stents.

Follow-up complications. None of the patients underwent repeat coronary bypass surgery. There was one case of posttraumatic bleeding associated with anticoagulant and antiplatelet therapy. No surgery or blood transfusion was necessary, and treatment was not discontinued.

Discussion

Clinical results (Table 1). This is the first report of intravascular stenting for saphenous coronary bypass graft stenosis. Our data show that, in 13 consecutively selected patients with disabling symptoms some of whom had undergone more than one surgical revascularization or previous balloon angioplasty procedure with recurrent restenosis, or both, satisfactory clinical and angiographic improvement could be maintained in most cases. Technically adequate implantation was achieved in all. In-hospital complications associated with the procedure were infrequent and minor. There were no in-hospital deaths and no cases of myocardial infarction or need for repeat coronary artery bypass surgery

Table 1. Individual Patient Data in 13 Cases

Patient No.	Age (yr) & Gender	CABG	AP	Target	NB	DIAM (mm)	Length (mm)	Follow-Up (mo)	AP	Restenosis	New Stenosis	Comment
1	70M	1	IV	LCx	1	3	15	15	0	No	Yes	Further stenting
2	51M	2	IV	RCA	1	4.5	20	26	0	No	Yes	Further stenting
3	55M	2	IV	LCX + LAD	2	4 + 4	23 + 19	12	III	Yes (2 ×)	No	Restenosis treated by atherectomy
4	62F	1	IV	LCx	1	3.5	23	11	0	No	No	—
5	63M	2	III	LCx	1	3.5	23	7	II	No	Yes	Further stenting
6	58M	1	IV	RCA	1	4	23	5	0	No	No	—
7	64M	1	UA	LCx	1	4	23	9	0	—	—	—
8	72M	1	IV	RCA	2	4 + 4	23 + 23	7	—	—	—	Died at 7 months of progressive heart failure
9	75M	1	III	LCx	2	5 + 5	23 + 23	5	0	No	No	—
10	66M	1	IV	LAD	1	6	22	4	UA	Yes	No	Restenosis treated with balloon angioplasty
11	69F	1	IV	LCx	2	5 + 5	21 + 21	5	II	No	No	—
12	54M	1	II	RCA	2	4 + 4	22 + 22	4	0	No	No	—
13	64M	1	IV	LAD	3	6 + 6 + 6	29 + 29 + 29	2	0	—	—	—

AP = Anginal symptoms before stenting or at follow-up graded according to the New York Heart Association classification; CABG = number of previous coronary artery bypass operations; DIAM = diameter of unconstrained implanted stents; Follow-Up = duration of follow-up; LAD = graft to the left anterior descending coronary artery; LCx = graft to the left circumflex coronary artery; Length = length of implanted stents; NB = number of stents implanted in one procedure; New Stenosis = occurrence of a new stenosis at the stent extremity (see text); RCA = graft to the right coronary artery; Target = location of target lesions; UA = unstable angina with transient electrocardiographic changes at rest.

during the hospital stay or the follow-up period. One patient with poor left ventricular function died of cardiac failure 7 months after stenting without any event suggesting acute graft closure.

Clinically, after one or more stent procedures, 10 patients were in improved condition and 8 of them were asymptomatic. Restenosis was observed within the stent in 2 (20%) of the 10 patients who underwent follow-up angiography. If the presence or absence of restenosis is inferred from the clinical data for the remaining three patients, the restenosis rates would be 3 (23%) of 13 per patient, 4 (29%) of 14 per graft and 4 to 5 (20% to 25%) of 20 per stent. These figures are lower than the high restenosis rate, usually >40%, observed after balloon angioplasty in the body of saphenous vein grafts (4–7,10,11).

Within-stent restenosis. The first of the two patients with within-stent restenoses (Patient 3) was initially treated for stenosis in one of his grafts by balloon angioplasty alone, but the improvement that ensued was only temporary. Transluminal atherectomy (8) was then performed with an excellent immediate result. Further experience and follow-up data are obviously needed but, when necessary and technically feasible, such an approach appears logical for the removal of restenosing tissue from within the stented segment. Patient 10 was treated by balloon angioplasty alone within the stented segment with good immediate angiographic and clinical results. Early experience in native coronary arteries for the treatment of within-stent restenosis (12) suggests that significant improvement of restenosis can be obtained with balloon angioplasty, but that recurrent restenosis will probably remain a problem in a large proportion of cases.

New stenosis at stent extremity. A new stenosis in the same graft, immediately proximal to the stented segment (Fig. 3), developed in three patients (in one of them twice). In each case it was a short concentric lesion and could be successfully dilated and stented with another device overlapping the previous one. Although these lesions may represent progression of graft sclerosis, it is likely that the shearing forces exerted at the stent extremities at each systole contributed to induce a localized reaction. The majority of the grafts treated in this series were diffusely atherosclerotic, and our approach was modified as experience was gained; whenever possible, we now implant longer stents, and often use several overlapping stents implanted during a single session when diffuse disease is obvious. This procedure has made it possible to successfully treat lesions that would otherwise have been poor candidates for balloon angioplasty alone.

Bypass grafts versus native coronary arteries. There are several theoretical reasons for thinking that vein grafts may constitute a particularly favorable target for stent implantation: 1) saphenous vein grafts are usually of a larger caliber than native coronary arteries and can accommodate larger and longer stents; as a rule, the entire area submitted to the barotrauma of balloon angioplasty can be covered with the stent. 2) Graft compliance is usually higher than that of coronary arteries and vasomotor tone or spasm, or both, are absent. Diameter mismatch between stent and recipient artery is thus not a problem.

Reports of stenting in native coronary arteries reveal conflicting results. The largest overall clinical experience with coronary implants is currently that obtained with the stent model used in this series (13–18). Initial success rates are excellent, but early thrombosis during the first days after implantation can remain a potential problem despite a clear-cut learning curve effect (19). Other groups have reported less favorable results (20), and this difference could well represent the effects of a different and less effective drug regimen during the postimplantation period.

Indications. Patient selection led to stent implantation in 13 (72%) of 18 procedures for which balloon angioplasty was attempted for vein graft lesions during the study period. One case was excluded because the lesion could not be crossed with the balloon, one because the lesion was a total occlusion and three because the anatomy was considered unsuitable. Experimental and clinical evidence (8,21) suggests that important diameter changes ("funnel shape") of the recipient vessel along the stented segment, small (i.e., <2.5 mm) luminal diameter or poor flow are potential risk factors for early stent occlusion. Furthermore, stent implantation is probably not desirable when the target lesion is situated at the distal anastomosis, and interferes with both anterograde and retrograde flow to the recipient vessel.

Although some candidates for balloon angioplasty in bypass grafts were thought unsuitable for stenting, some of the patients who did receive a stent were poor candidates for balloon angioplasty alone, because of several previous recurrences after balloon dilation. Stent implantation also made it possible to treat old grafts with diffuse disease without added complications. This may be because stenting improves initial rheology by smoothing the endoluminal surface (17) and also because it probably prevents embolization of friable atherosclerotic material.

All patients in our series underwent graft stenting at least 1 year (median 4 years, range 1 to 16) after their last coronary bypass operation. The lesions were thus likely to be due to graft atherosclerosis in most cases (22,23), compounded in some with postangioplasty restenosis. It remains to be seen whether stenting is equally effective for the early focal fibrointimal hyperplasia sometimes observed in grafts during the first months after surgery (22,24).

Conclusions. These initial data are encouraging and suggest that stenting may offer an alternative treatment to selected patients who suffer from recurrent angina with graft stenosis after surgical coronary revascularization. However, further work needs to be done to assess outcome over a longer period of time and to better understand the complex interactions between stent and recipient vessel. Modifica-

tions in stent design may be necessary to improve results. Only then will it be possible to define guidelines and recommendations for routine clinical use.

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