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EDITORIAL REVIEWS

Intracoronary Stents: Will They Fulfill Their Promise as an Adjunct to Angioplasty?*

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Coronary angioplasty as it is now performed has several limitations, including abrupt early arterial closure and delayed restenosis. To obviate these problems and to enhance the safety of the technique, several intracoronary stenting devices have been developed and are under investigation. This report reviews the scientific rationale behind stenting, the results of stenting in animal models and the early results in humans. In early clinical investigation, restenosis appears uncommon but abrupt, presumably

In 1977 Gruentzig et al. (1), expanding on the work of Dotter and Judkins (2), performed the first coronary angioplasty in humans. Today, this procedure has revolutionized the treatment of patients with coronary artery disease, and >200,000 coronary angioplasties are performed annually in the United States. That successful angioplasty may provide patients with stable or unstable angina ≥ 10 years of relief from their symptoms has now been established (3), and trials are underway to determine whether coronary angioplasty or bypass surgery should be performed in most patients with multivessel coronary disease. The use of coronary angioplasty has now been successfully extended to patients presenting with acute myocardial infarction (4), although logistic and financial considerations suggest that its emergency use in this setting be limited to patients who have had unsuccessful or who have contraindications to intravenous thrombolytic therapy (5).

thrombotic, occlusion has been reported despite aggressive anticoagulation. As long as the potential for this problem remains and the long-term consequences of placing these devices into arteries of great functional importance remain unknown, stent placement must be undertaken with great caution and should be performed under carefully monitored circumstances with meticulous patient follow-up.

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Limitations of the Current Angioplasty Technique

Abrupt coronary closure. Coronary angioplasty as it is now performed has several limitations. First, major ischemic complications develop in about 4% to 5% of elective procedures (6,7). Although patients at highest risk of complications can be identified, abrupt coronary closure occurs to a certain extent unpredictably (8,9). The mechanism of abrupt closure appears most often to be coronary dissection, often with secondary superimposition of thrombus formation and coronary spasm (10). Even though the use of prolonged balloon inflations, intracoronary thrombolytic agents and nitrates can alleviate ischemia and obviate the need for emergency bypass surgery in some instances, surgery was required in 3.4% of patients in the 1985–1986 National Heart, Lung and Blood Institute Registry (7). Even in the best of surgical centers, when a patient with ongoing ischemia is sent for coronary bypass surgery, there is a 27% likelihood of Q wave infarction, and this marker of lost myocardium predicts a poor 5 year survival rate (11).

Restenosis. Second, new stenosis at the site dilated (restenosis) occurs in 16% to 34% of patients (12,13), and may occur in >40% of patients undergoing coronary angioplasty of stenosis located in the proximal anastomosis or body of saphenous vein bypass graft, proximal portion of the left anterior descending coronary artery, ostium of the right coronary artery or points of angulation or total occlusion (14–18). Restenosis also occurs more commonly after a suboptimal angioplasty result (13), and seems in most in-

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	Expanded Configuration*	Composition	Deployment	Flexible	Length (mm)
Wallstent	ARD-	0.08 mm stainless steel filaments	PTCA balloon/ self-expanding	Yes	15 to 23
Palmaz design		0.015 mm stainless steel filaments	PTCA balloon- expandable	No†	15
Gianturco design		0.015 mm stainless steel filaments	PTCA balloon- expandable	Yes	20

Table 1. Characteristics of Coronary Stents Currently Available for Human Investigation

*Full length not shown; \dagger flexible articulated design has recently been approved by the U.S. Food and Drug Administration for investigation. PTCA = percutaneous transluminal angioplasty.

stances to be caused by myointimal proliferation, perhaps consequent to growth factors released by platelets adherent to the damaged coronary intima or media (19,20). Stenosis elasticity may also contribute to restenosis. To date, no medical intervention to prevent restenosis has been unequivocally successful.

Old coronary occlusion. Third, angioplasty is severely limited in achieving long-term (21) or even short-term success in coronary vessels that have been occluded for >8 to 20 weeks (18,22). By this time, the occlusion is often too firm to cross, and even if the occluded segment can be successfully dilated, restenosis is common (18,21,22).

Recurrent ischemia after myocardial infarction. A fourth major limitation of the technique occurs when it is applied in the setting of acute myocardial infarction. Even though initial technical success may be achieved in >80% of patients (23,24), 15% to 25% will have recurrent ischemia before hospital discharge (5,23,25), and a further 19% to 39% will have restenosis within 6 months (26,27). In this setting, the presence of thrombus even before coronary angioplasty is initiated, the sluggish coronary flow due to downstream myocardial edema and the further intimal trauma caused by the angioplasty balloon all predispose to recurrent thrombus formation and ischemia.

Recently, a number of alternatives or adjuncts to coronary angioplasty have been developed to overcome one or more of these limitations. These include intracoronary stents, atherectomy or pulverizing devices and lasers.

Intracoronary Stents (Table 1)

As early as 1969, Dotter (28) proposed and placed a tubular coiled wire stent graft to prevent the recurrence of

peripheral artery stenosis after angioplasty. Despite a several year hiatus in implementation of the concept, a variety of stent designs are now being evaluated in an attempt to circumvent many of the shortcomings of current angioplasty techniques. Self-expanding spiral (29), zigzag (30) and wire mesh metal stents (31), thermal memory alloy stents (32,33), balloon-expandable metal stents (34) and thromboplastic (35) and biodegradable stents have been tested experimentally and at least four stent designs have been deployed as an adjunct to coronary angioplasty in a total of nearly 200 patients to date.

The ideal coronary stent and currently available stents. What can we expect from this concept and technology? The ideal coronary stent would be 1) flexible enough to allow its placement, 2) biocompatible with the coronary artery into which it is placed and the blood components that must repeatedly traverse it, 3) durable or degradable, and 4) easily and safely deployed. Once placed into the coronary artery, it would lessen the risk of vessel closure by widening the lumen, thereby improving blood flow and decreasing blood turbulence and by decreasing the area of disrupted arterial media exposed to elements predisposing to thrombus formation. Furthermore, the radial stress that may mediate medial thickness may be reduced, thus potentially leading to medial atrophy and a lessened risk of restenosis.

Currently available stents fall short of this ideal. The four stents undergoing investigation for use in human coronary arteries (thermal expandable coil, the Medinvent Wallstent and the stents developed in large part by Gianturco [30] and Palmaz et al. [34]) as well as other devices in earlier stages of development will be reviewed in relation to this ideal.

Flexibility. A certain degree of stent flexibility is a prerequisite for its deployment through the curves of the guiding catheter and a possibly tortuous artery to the point of dilation. However, cyclic stretching appears to augment the smooth muscle cell activity that may lead to restenosis and thereby be counterproductive (36). A direct comparison of degrees of intimal hyperplasia induced by stent placement in experimental animals may be misleading because of differences in experimental design. However, support for the importance of repeated stretching on stent-induced intimal hyperplasia comes from a comparison of the 200 to 450 μ m intimal thicknesses reported after 6 months of implantation of the flexible Wallstent and Gianturco coil stents (3.0 to 5.0 mm devices) (37-39) with the 100 μ m thickness reported after the use of the rigid Palmaz stent (40) under similar conditions. Intimal hyperplasia after use of the Wallstent in humans has been documented by analysis of tissue fragments removed by percutaneous atherectomy (Simpson J, personal communication). One potential solution to this problem proposed by Schatz et al. (41) would be to construct a stent with multiple short articulated segments; preliminary work in animal preparations with such a stent is encouraging, and this stent has recently been approved by the U.S. Food and Drug Administration for limited experimental use in humans. Studies by Schatz et al. (40) suggest that intimal hyperplasia may reach its maximal thickness 8 weeks after implantation and then regress, but this possibility needs to be confirmed in human studies.

Biocompatibility. The biocompatibility of a stenting device is dependent on its surface chemistry, surface energy and surface texture, both at the time of initial implantation and after the effects of prolonged exposure to the arterial wall and blood elements. Because endothelium cannot be grown on bare metal surfaces and requires the presence of a thin layer of fibrin and thrombus, limited thrombus formation is essential for healing. The brisk anterograde flow allowed by stent placement facilitates the dynamic process of orderly but limited fibrin deposition. Surface protein absorption is highest for the Group 1B elements such as silver and copper, as well as the transitional elements such as platinum (42) and, thus, these metals are unsuited for use in stents. Thrombogenicity appears to be directly related to wire thickness and stent porosity (37).

The Gianturco-Roubin and Palmaz stents now used utilize 0.015 mm wires, whereas the Wallstent uses considerably thicker (0.08 mm) filaments. Perhaps as a result, 13 of 43 animals in one series in which the Wallstent was used developed partially or totally occlusive thrombosis (31), whereas thrombosis has been much less common after deployment of the Palmaz stent (40) and has not been reported with the Gianturco stent except in 3.0 mm arteries with generally oversized stents (stent/artery ratio >1.2) when the animals were not kept on long-term antiplatelet medications (38,43–45). The thrombogenicity of stainless steel may be reduced by buffing to minimize surface defects, and by administering dextran during the implantation to minimize attraction of electronegative platelets to the electropositive metal (46). Heparin bonding and endothelial cell seeding have also been proposed to decrease stent thrombogenicity. Less certain is the thrombogenicity of nitinol, a nickel-titanium alloy that "memorizes" its shape after annealing at $>500^{\circ}$ C, but after cooling can be shaped for deployment over a guidewire only to resume its prior shape after warming to body temperature (47).

Durability. Long-term biocompatibility will depend on the effects of surface oxidation, fretting corrosion and repeated stretching within the arterial wall (48). Results of stent explanation and examination have been reported for stents in place for up to 2 years, and angiographic documentation of patency now extends to 3 years (Palmaz J, personal communication), but the truly long-term effects are not known. Biodegradable stents are currently under development.

Safety and ease of deployment. Safe stent deployment requires that stents be flexible, radiopaque and expand reliably to a predetermined size. The issue of flexibility has been discussed. The desirability of minimizing wire thickness to reduce thrombogenicity has placed the radiopacity of available stainless steel stents at or below the limits of resolution of most commercially available laboratory systems. As a consequence, premature deployment of a stent because of slippage off the dilation balloon may initially be unnoticed, and precise deployment may be difficult. More radiopaque metals such as gold or platinum are expensive and potentially thrombogenic. Tantalum stents appear promising (49), but biocompatibility testing is incomplete at this time (Schatz R, personal communication). Devices that cannot be reliably expanded have the added risk of undersizing (stent/artery ratio <1.0) and stent migration or oversizing (stent/artery ratio ≥ 1.2) and added medial trauma. Nitinol stents may expand prematurely in the guiding catheter and prevent deployment. Balloon-expandable stents have the advantage of precise expansion to the limits of the delivery balloon. Finally, the stent expansion ratio (expanded/compressed) must be $\geq 4:1$ to allow the compressed stent to pass freely through the guide catheter, yet be large enough once expanded to support the arterial wall.

Clinical Trials in Coronary Artery Disease

The Wallstent. Because the behavior of endovascular protheses differs slightly in larger arteries and in veins, this discussion will focus on preliminary reported results of stent placement in coronary arteries. To date, the largest clinical experience with stent placement in human coronary arteries has been with the Wallstent, although as just noted, its preclinical "track record" is not the best. Sigwart (personal communication) has implanted over >100 stents to date and he and his colleagues (50,51) have formally reported preliminary results of implantation to prevent restenosis or treat abrupt closure in 56 patients. Patients were treated with aspirin (1 g) the day before the procedure; with heparin, calcium channel blocking agents and intracoronary urokinase during the procedure and with aspirin (990 mg), dipyridamole (225 mg), nifedipine (60 mg) and acenocoumarin daily after the procedure. More recently, the doses of aspirin and dipyridamole have been reduced to 100 and 400 mg daily, respectively, and sulfinpyrazone (400 mg daily) was added. Of the 44 patients treated to prevent restenosis, 43 had a patent stent at the 24 h follow-up angiogram. Thirtyeight patients (86%) had a good long-term clinical result, but there have been two documented reocclusions, two presumed reocclusions, one documented restenosis and four late deaths (10 events in six patients). One patient who died suddenly at home had not been taking his prescribed medications. Of the 12 patients who received a stent to treat acute occlusion, none developed a Q wave infarction or died, and none of the 6 patients restudied developed restenosis (51).

Puel et al. (52) reported early stent occlusion in 12 of 33 patients treated with the same Wallstent device, but their anticoagulant regimen was less intensive and their patient selection may have been different from that of the Lausanne group. Similarly, Bertrand et al. (53) reported early thrombotic occlusion in 4 of 14 patients. Late restenosis, as opposed to reocclusion, has been reported (50–53) in five patients from these Wallstent series, and has been related to poor distal run-off or failure to stent the entire length of the dilated segment.

The Gianturco coil stent. Nine patients have had the Gianturco coil stent implanted as a bridge to bypass surgery in a preliminary study designed to assess the safety and efficacy of stent deployment by Roubin et al. at Emory University (Roubin G, personal communication). In these patients, the stent appeared to function well. In one patient, the stent could not be deployed because of inadequate balloon inflation. Subsequently, four patients have had this stent implanted without later surgery, and, with brief follow-up, all have been without complication.

The Palmaz stent. Schatz and Palmaz (54) have reported their initial experience with the Palmaz stent in patients treated to prevent restenosis; their report includes our own experience. The rigidity of the nonflexible stent has limited its deployment to arteries that provide an easy approach to the stenosis and to stenoses that are located on straight segments of artery. The articulated flexible stent has been implanted in countries outside the United States. In the updated experience (Schatz R, personal communication), stent deployment has been successfully achieved in 18 of 20 patients, and in the 2 patients with unsuccessful placement, there were no acute complications. One patient has had protocol-mandated angiography at 6 months and did not have restenosis. The remaining patients have had negative exercise test results (1 to 6 month follow-up). Each of the other stents has been placed in fewer than five patients in the United States, and the experience has been even more difficult to evaluate.

Unresolved Issues

Will stents obviate the need for bypass surgery for acute ischemic complications of coronary angioplasty? Cadaver studies (55) have confirmed the ability of stents to tack up intimal debris and seal off the subintimal space. The initial short-term results reported by Sigwart et al. (51) and Roubin (personal communication) are encouraging and suggest that, at least in some patients, closure-related ischemia can be eliminated by stent placement. However, in most instances to date, the stenosis treated has been proximal and readily accessible. Current stents may not be reliably useful in tortuous arteries or for distal occlusions and, therefore, perhaps offer little advantage over available "bail out" catheters (56) unless long-term stent patency can be expected.

Will stents maintain long-term vessel patency? If the problem of abrupt vessel closure resulting from obstructive thrombus formation can be overcome, stents may be able to provide scaffolding for the limited and organized intimal proliferation required for long-term vessel patency. Interestingly, all arterial segments stented >3 months that have been analyzed microscopically by Palmaz et al. (46) have shown medial atrophy. This may be the consequence of the stent's protecting the media from the effect of the artery's pulsatile flow, as suggested by the often noted attenuation of the media in heavily calcified human coronary arteries (57). Supportive data of this concept also come from the work of Thubriker et al. (58), whose dental acrylic casted arterial segments developed much less atherosclerotic change over time than did the noncasted segments. If the stent-induced reduction of medial stress and consequent medial atrophy diminish the likelihood of restenosis and the long-term effects of stent "wearing" do not predispose to other problems, then intracoronary stenting may well prove to be a useful adjunct to balloon angioplasty for the management of patients with coronary artery disease. However, as long as the problem of abrupt thrombotic occlusion remains and as long as the long-term consequences of placing these foreign devices into arteries of great functional importance remain unknown, stent placement, like other intracoronary device development, must be undertaken with great caution and performed only under carefully controlled circumstances with meticulous patient follow-up.

Finally, if initial safety and efficacy of stenting and other adjunctive device treatments can be demonstrated, a randomized comparison of their efficacy with that of standard balloon angioplasty will be required to assess their proper role in the treatment of coronary artery disease. We express our gratitude for the assistance provided by Richard Schatz, MD and Julio Palmaz. MD, the careful manuscript review by Ulrich Sigwart. MD and the secretarial assistance provided by Judy Hanson.

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