Clinical Experience With the Palmaz-Schatz Coronary Stent
Initial Results of a Multicenter Study

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Stenting of native coronary arteries with a balloon-expandable stent was attempted in 226 patients after elective angioplasty. Delivery of the device was successful in 213 (94%) of the patients. Of these, 39 received aspirin and dipyridamole only (group 1) and 174 received aspirin, dipyridamole, and warfarin for 1–3 months (group 2). There was no abrupt closure (≤1 day) or perioperative death in either group. In-hospital or perioperative complications in group 1 compared with group 2 were as follows: subacute closure (1–14 days), seven (18%) patients versus one (0.6%) patient, respectively, p<0.0001; myocardial infarction, five (13%) patients versus one (0.6%) patient, respectively; condition requiring urgent bypass surgery, one (2.5%) patient versus no patients, respectively. Thus, the incidence of major complications such as death, myocardial infarction, or a condition requiring urgent bypass surgery was 15% in group 1 and 0.6% in group 2. Clinical follow-up revealed that 92% of the patients were asymptomatic at 3 months after stenting compared with 6% before stenting (p<0.0001). Of the 13 patients who were symptomatic, nine underwent cardiac catheterization and, ultimately, successful elective coronary angioplasty or bypass surgery. We conclude that a high delivery success rate can be expected with this device and that clinical thrombosis is less frequent in anticoagulated patients than in nonanticoagulated patients. Furthermore, in this selected patient population, coronary stenting results in a low incidence of in-hospital and perioperative complications. Clinical success, defined by absence of symptoms, appears to be sustained at 3 months. (Circulation 1991;83:148–161)

Percutaneous transluminal coronary angioplasty (PTCA), first reported in 1977,1 represents a major advance in cardiovascular therapeutics; over 225,000 procedures were performed in 1988.2 Improved operator technique and advanced equipment designs have resulted in an increase in primary success rate from 67% in 1984 to 87% in 1986.3 Despite these improvements, acute closure...
(occurring in 3–5% of patients\(^4\)–\(^6\)) and restenosis (occurring in 25–40% of patients\(^7\)–\(^8\)) remain as serious limitations to both the short- and long-term success of PTCA. Furthermore, perioperative occlusion after PTCA is an ominous predictor of both in-hospital and late ischemic complications,\(^9\)–\(^11\) prompting investigators to explore permanent vascular implants as an alternative method to maintain vessel patency after angioplasty.\(^12\)–\(^29\) One such device is a balloon-expandable intracoronary stent developed by Palmaz and colleagues.\(^18\)–\(^23\),\(^25\)

The focus of this report is to describe the procedural results and short-term follow-up obtained during a multicenter investigation of this device.

Methods

Patient Selection

Patients were enrolled prospectively and consecutively into this multicenter study from December 1987 to September 1989. All United States centers participating in the stent (Johnson&Johnson, Warren, N.J.) protocol under the specific indications for use as outlined in the investigational device exemption, approved by the Food and Drug Administration (FDA), are represented in this series. Excluded from this analysis specifically are patients enrolled under subsequent investigational device exemptions with separate indications for use, such as saphenous vein bypass graft lesions, abrupt closure, or acute myocardial infarction. Data from centers outside the United States not participating in this protocol are also excluded from the series.

Clinical entry criteria included 1) symptomatic coronary artery disease manifested by objective evidence of myocardial ischemia, either ST depression or elevation during exercise stress testing, or a reversible perfusion defect by thallium scintigraphy, 2) angiographic demonstration of single- or multiple-vessel coronary disease with a target lesion diameter stenosis greater than 70% (determined by individual operator techniques), and 3) angiographic demonstration of ipsilateral or contralateral collaterals (of any degree) to the distal vessel beyond the lesion site. All patients were candidates for coronary artery bypass surgery and were able to give informed consent for use of this investigational device. There were no specific age or ejection fraction limitations for study entry.

The exclusion criteria included the following: 1) tortuosity of the vessel proximal to or in the region of the lesion, 2) obstruction of the left main coronary artery unless protected by patent bypass grafts to at least one of the distal vessels, 3) recent acute myocardial infarction, 4) large diseased-side branch vessels in proximity to the lesion, 5) diffuse distal disease that would compromise outflow from the target lesions, 6) disease at anastomotic sites or the body of saphenous vein bypass grafts, 7) abrupt closure after PTCA, 8) associated congenital, myocardial, or valvular heart disease.

Stent Design

Two types of stents were used in this study. The first was an early prototype developed by Palmaz and colleagues\(^18\)–\(^23\) that consisted of a rigid slotted stainless-steel tube designed to mount coaxially over commercially available balloon catheters (Figure 1a). The stent measures 1.6 mm in diameter and 15 mm in length and is delivered percutaneously to the target site. The mechanical properties and biocompatibility profile of this stent have been previously described in multiple animal models.\(^18\)–\(^20\),\(^21\),\(^29\)

The second stent used in this study was developed by Schatz et al\(^25\) as a modification of the Palmaz design to improve flexibility (Figure 1b). This stent is composed of two shorter (7 mm) segments of slotted tubes connected by a small (1 mm) bridging strut, a design that permits longitudinal flexibility while preserving the radial noncompliance of each component segment upon expansion. The favorable biocompatibility properties of this modified design have also been reported previously in animals.\(^25\) Except for the first eight articulated stents, which had eight rows, all of the stents used in this study had 12 rows of slots.

Stent Implantation Procedure

After Institutional Review Board approval and informed consent, patients were brought to the catheterization laboratory in a fasting and sedated state, and catheterization was performed by either the brachial or femoral approach.

Rigid Stent

Balloon dilatation of the target lesion was performed in all patients by use of standard angioplasty techniques before stenting. Rigidity of the early prototype prevented antegrade passage of the stent-loaded balloon through most guiding catheters. Therefore, the balloon catheter was first passed antegrade through a preselected guiding catheter (multipurpose or hockey-stick curves) so that the balloon extended well beyond the tip of the guiding catheter. A sterile balloon-expandable stent was then mounted on the balloon, mechanically cramped, and then withdrawn into the tip of the guiding catheter. The guiding catheter was then advanced to the aortic root and engaged in the appropriate coronary ostium.

Next, the wire was passed antegrade across the freshly dilated target lesion, followed by the stent-loaded balloon. Once centered, the stent was deployed by balloon inflation to 6–10 atm for 5–10 seconds. If the expanded stent diameter appeared too small, dilatation with a larger balloon was performed to further expand the stent to the appropriate diameter. Overdilatation by about 10% was considered optimal.\(^22\) Tandem placement with the rigid stent requires that the distal stent be placed first.

Articulated Stent

The technical advantage of this modified stent is that simple exchange techniques can be used for
delivery. After routine dilatation, a stent-loaded balloon catheter was passed antegrade over a guidewire. Because the shorter segments “articulate” or flex around curves, the stent passes easily through most 8F or 9F guiding catheters. Once delivered to the target site, expansion was accomplished with a single balloon inflation of 6–10 atm for 5–10 seconds. If further expansion was required, the guidewire was left in place and the next larger–sized balloon was passed using standard exchange techniques. Tandem stents could be placed without removing the guidewire, offering an advantage over the rigid prototype.

**Stent Retrieval**

In the event of inability of the stent to pass the lesion, retrieval of the device was accomplished by withdrawal of the guiding catheter to the femoral sheath before attempting to pull the stent-loaded balloon into the guiding catheter.

**Quantitative Coronary Analysis**

Quantitative coronary analysis was performed with the use of a computer-based coronary angiography analysis system with automatic edge detection (ADAC, Milpitas, Calif.). Paired cine frames, in orthogonal views wherever possible, were selected from the preangioplasty and post-stent cineangiograms (n=138; the remainder of the films was unavailable) and then reviewed by three observers. The day-to-day observer variability was 0.16 mm for absolute diameter and less than 5% for percent steno-
sis. Quantitative measurements of stenosis diameter (in millimeters) were determined by using the guiding catheter as a scaling device. Minimal lumen diameter was reported and typically occurred at the central gap within the stent. Proximal and distal segments, considered to be without coronary disease and outside the stented segment, were selected and averaged; this average value was considered to be the diameter of the normal reference vessel and was used to determine the percentage diameter stenosis.

Drug Regimen

The following drug regimen was based on thrombogenicity testing in animals\textsuperscript{21}: Aspirin (325 mg p.o. daily) and dipyridamole (75 mg p.o. three times a day) were begun at least 24–48 hours before stenting, with a calcium channel blocker beginning at least 1 day before the procedure. All patients were treated with low molecular weight dextran 40 (100 ml/hr i.v.) 2 hours before stent deployment and continued for a total dose of 1 l. Heparin (10,000 units) was given as an initial intravenous dose in the catheterization laboratory followed by approximately 2,500 units/hr thereafter during the procedure. Activated clotting times were measured when available and maintained at 2 to 2.5 times baseline. Intracoronary urokinase (up to 500,000 units) was administered only if thrombus was visible before or after stent placement. Intracoronary nitroglycerin (200 μg) was given once before and once after stent deployment. After the procedure, a heparin infusion was begun to maintain a partial thromboplastin time at approximately 1.5–2.5 times control and continued for at least 24 hours. Aspirin, dipyridamole, and calcium channel blockers were continued for 3 months, after which the dipyridamole and calcium channel blockers were discontinued. Warfarin was not administered routinely to the first 39 patients, but due to subacute thrombosis, all patients were treated thereafter with warfarin (prothrombin time between 16 and 18 seconds) in addition to aspirin and dipyridamole. Warfarin or subcutaneous heparin was continued for 1–3 months unless intercurrent bleeding complications required therapy adjustment.

Poststent Course and Evaluation

Sheaths were removed between 2–24 hours after stenting, depending on operator preference, and after heparin had been discontinued for 2–4 hours. Heparin was restarted 2–4 hours after sheath removal. Broad spectrum antibiotics were given for 24 hours intravenously if sheaths were left in place for more than 2 hours after the procedure. Repeat angiography of the treatment vessel was performed at 24 hours in the initial 66 patients of the study. In the absence of complications, or oral anticoagulation therapy, patients were discharged approximately 48 hours after stent placement. If oral anticoagulants were used, discharge was delayed until the prothrombin time reached approximately 16–18 seconds and the heparin could be safely discontinued (usually 2 or 4 days after stent placement).

Posthospitalization Course and Evaluation

Patients were seen at 2 weeks, and 1, 2, and 3 months. Clinical status up to 3 months only is the subject of this paper. Diagnostic angiography was performed at operator discretion at any time. Treatment with antibiotics similar to infective endocarditis prophylaxis was recommended for 3 months after stenting.

Definition of End Points

The following end points were examined: 1) successful delivery: complete passage of the stent across the target lesion with full expansion of the stent to the desired diameter, 2) failed delivery: failure to pass the stent through the guiding catheter into the coronary artery, failure to pass it completely across the target lesion, or failure to expand the stent to its desired diameter, 3) proximal deployment: those instances of failed delivery when the stent could be advanced only partially across the target lesion but was deployed nonetheless by full expansion, 4) acute closure: total thrombosis of the stent within 24 hours of delivery, and 5) subacute closure: total stent thrombosis between 24 hours and 2 weeks after delivery.

Statistical Analysis

Interactions between categorical variables such as the involved vessel and delivery success were analyzed by Fisher’s exact test or the χ² test. Treatment effects on continuous variables such as percent stenosis of object vessel were examined by the two-tailed t test. Distributions of continuous data are described as mean±SD. Effects were interpreted as significant when the null hypothesis could be rejected at the 95% confidence level.

Results

Patient Population

After informed consent was obtained, 226 patients were enrolled prospectively into this FDA-approved protocol. Table 1 shows the demographics of the subject population. One hundred seventy-four were men and 52 were women. The mean age was 56 years with a range of 26–86 years. One hundred seventy-eight (79%) patients had single-vessel disease, and 48 (21%) had multivessel disease. Forty-seven (21%) patients had total occlusion; the remainder had severe stenoses. Sixty-nine patients presented as candidates for a primary angioplasty procedure; the remainder presented with restenosis: 61 with a first, 61 with a second, 24 with a third, seven with a fourth, and four with a fifth restenosis. Thus, 157 (69%) patients had previous coronary angioplasty with clinical and angiographic restenosis. The distribution of vessels in which stenting was attempted was as follows: right coronary artery, 134 patients; left anterior descending coronary artery, 74 patients; circumflex/
TABLE 1. Demographics of the Patient Population

<table>
<thead>
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<th>Characteristic</th>
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<th>%</th>
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</tr>
<tr>
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<td></td>
</tr>
<tr>
<td>Male</td>
<td>174</td>
<td>77</td>
</tr>
<tr>
<td>Female</td>
<td>52</td>
<td>23</td>
</tr>
<tr>
<td>Age</td>
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<td></td>
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<tr>
<td>Range (yr)</td>
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<td></td>
</tr>
<tr>
<td>Mean (yr)</td>
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<td></td>
</tr>
<tr>
<td>Hypertension</td>
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<td>45</td>
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<td>Diabetes mellitus</td>
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<td>17</td>
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<td>History of smoking</td>
<td>166</td>
<td>73</td>
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<td>Hypercholesterolemia (&gt;225 mg%)</td>
<td>136</td>
<td>60</td>
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<tr>
<th>Canadian Cardiovascular Society angina class</th>
<th>No.</th>
<th>%</th>
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<td>17</td>
<td>8</td>
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<td>3</td>
<td>72</td>
<td>32</td>
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<tr>
<td>4</td>
<td>83</td>
<td>37</td>
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<td>Single-vessel disease</td>
<td>178</td>
<td>79</td>
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<td>Multivessel disease</td>
<td>48</td>
<td>21</td>
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<tr>
<td>Ejection fraction (%)</td>
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<tr>
<td>Prior myocardial infarction</td>
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<td>41</td>
</tr>
<tr>
<td>Total occlusion</td>
<td>47</td>
<td>21</td>
</tr>
<tr>
<td>Subtotal stenosis</td>
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<td>79</td>
</tr>
<tr>
<td>Primary angioplasty</td>
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<td>30</td>
</tr>
<tr>
<td>Secondary angioplasty</td>
<td>157</td>
<td>70</td>
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<td>Third restenosis</td>
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<td>11</td>
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<td>Fourth restenosis</td>
<td>7</td>
<td>3</td>
</tr>
<tr>
<td>Fifth restenosis</td>
<td>4</td>
<td>2</td>
</tr>
</tbody>
</table>

obtuse marginal branch, 17 patients; left main coronary artery, one patient (Table 2).

Stent Delivery

Successful delivery of 299 stents was accomplished in 230 lesions in 213 patients. One hundred seventy-five patients received 188 stents for 188 lesions (single stents), and 42 patients received 108 stents in tandem for 42 lesions (multiple stents). One patient received a single stent for one lesion and two tandem stents for another (Table 3). Failed delivery occurred with 22 stents in 19 patients. Of these stents, 11 were successfully withdrawn, three were partially deployed within or proximal to the lesion, and eight were embolized systemically during attempted withdrawal into the femoral sheath without clinical sequelae. Of these 22 failed deliveries, six occurred with the rigid stent, and 16 occurred with the articulated stent. Six patients also had successful delivery after failed delivery. The overall delivery success rate was therefore 299 of 321 (93%) stents and 213 of 226 (95%) of patients.

Rigid Stent

Placement of 30 rigid stents was attempted in the right coronary arteries of 23 patients. Twenty-four were successfully delivered in 17 patients, for a primary success rate of 80%. Five of the six failed deliveries occurred as a result of stent inflexibility, and one of six was due to snagging proximal to the lesion. One stent was deployed proximal to a lesion that was incompletely dilated, two were successfully removed from the patient, and three were embolized systemically during withdrawal into the femoral sheath without clinical sequelae.

Articulated Stent

The delivery success rate improved in patients who received the articulated stent. Two hundred seventy-five (95%) of 291 stents were delivered successfully. In 16 attempts, the stent failed to cross the target as a result of snagging at or before the lesion or snagging against a previously placed stent. Eight of these stents were successfully withdrawn, but five of them embolized (four patients) systemically and two were deployed proximally. In one patient with a severe dissection, the stent was deployed partially within the lesion. When a second stent could not be passed through the first, this patient was referred for uncomplicated bypass surgery. Another patient in whom stent delivery failed received routine angioplasty but died of a myocardial infarction 9 days after the procedure.

TABLE 2. Distribution of Vessels Attempted

<table>
<thead>
<tr>
<th>Location</th>
<th>Rigid</th>
<th>Articulated</th>
<th>Total</th>
</tr>
</thead>
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<tr>
<td>RCA</td>
<td>17</td>
<td>117</td>
<td>134</td>
</tr>
<tr>
<td>LAD</td>
<td>0</td>
<td>74</td>
<td>74</td>
</tr>
<tr>
<td>Circ/OMB</td>
<td>0</td>
<td>17</td>
<td>17</td>
</tr>
<tr>
<td>Left main</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

RCA, right coronary artery; LAD, left anterior descending coronary artery; Circ/OMB, circumflex/obtuse marginal branch; Left main, left main coronary artery.

TABLE 3. Stent Distribution for 230 Lesions in 213 Patients

<table>
<thead>
<tr>
<th>Stents</th>
<th>Rigid</th>
<th>Articulated</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single</td>
<td>12</td>
<td>158</td>
<td>188*</td>
</tr>
<tr>
<td>Multiple</td>
<td>2</td>
<td>4</td>
<td>23</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>0</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>4</td>
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<td>2</td>
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<tr>
<td></td>
<td>5</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>17</td>
<td>195†</td>
<td>296†</td>
</tr>
</tbody>
</table>

*Eighteen patients received more than one single nontandem stent in the same vessel.
†One additional patient had a single stent for one lesion and two stents in tandem for another.
Analysis of Failed Delivery

Analysis of those variables that contributed to successful and failed delivery of the stent revealed that successful delivery was more likely when the articulated stent was used instead of the rigid stent (95% versus 80%, \( p<0.02 \)). Successful delivery was more common in the right and left anterior coronary arteries compared with the circumflex artery (93% versus 83%, \( p<0.03 \)), in proximal (first third) versus distal (beyond the first third) lesions (97% versus 88%, \( p<0.05 \)), and when there was no evidence of dissection after the initial PTCA (96% versus 83% with dissection, \( p<0.04 \)). There was no difference in delivery success rate between primary and restenosis lesions.

Finally, successful delivery tended to improve with operator experience, ranging from 89% in the first 50 patients versus 98% in the last 50 patients stented (\( p<0.004 \) for linear trend) (Figure 2). Coincident with an apparent improved delivery success rate later in the series is the observation that fewer stents were placed per patient (1.22 versus a peak of 1.58 earlier in the series), reflecting avoidance of patients with longer and more difficult target lesions.

Successful Delivery Outcome

Of the 213 patients who had successful delivery of either the rigid or the articulated stent, 39 were discharged without anticoagulation (group 1), two were treated with subcutaneous home heparin (operator preference), and the remainder (172 patients) were treated with warfarin (group 2). Percent stenosis decreased from 73±15% before angioplasty to 16±12 after stenting (\( p<0.0001 \)). Follow-up angiography 1 day after stenting in the first 66 patients revealed no change in the vessel diameter at the stented site or migration of the device (Figure 3). The mean final stent diameter was 2.7±0.5 mm. The target artery diameter ranged from 2.0 to 4.0 mm.

Three patients who received the rigid stent required intracoronary urokinase ranging in dosage from 70,000 to 500,000 units for asymptomatic nonocclusive thrombus seen within the lesion before placing the stent. None of these patients received anticoagulation therapy on discharge. Two patients who received the articulated stent required intracoronary urokinase ranging in dosage from 75,000 to 250,000 units for luminal thrombus after stent delivery. Figures 4–6 illustrate angiographic examples of successful stent delivery.

Complications

Table 4 reveals the complications of those patients who did not receive anticoagulation after successful stent delivery (group 1) versus those who did (group 2) and in the total population in whom stent delivery was attempted.

Group 1: Nonanticoagulated. Of the 39 patients in this group, 17 received the rigid stent and 22 received the articulated stent. No patients suffered acute closure, but seven (18%) patients (all of whom received articulated stents) developed subacute thrombotic closure within 2–11 days after stenting, five of whom sustained myocardial infarction. One remains asymptomatic with excellent collaterals, one underwent elective bypass surgery, one underwent urgent bypass surgery after successful recanalization, three remained patent angiographically after successful recanalization (although each suffered non-Q wave myocardial infarction), and one patient suffered a Q wave infarction (creatine phosphokinase 2,800) and remained occluded after failed attempts at re-
Table 4. Complication Summary

<table>
<thead>
<tr>
<th>Complication</th>
<th>Successful delivery (n=213)</th>
<th>Failed delivery (n=13)</th>
<th>Total (n=226)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Group 1 (n=39)</td>
<td>Group 2 (n=174)</td>
<td></td>
</tr>
<tr>
<td>Acute closure</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Subacute closure</td>
<td>7 (18%)</td>
<td>1 (0.6%)†</td>
<td>8 (3.7%)</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>5 (13%)</td>
<td>1 (0.6%)†</td>
<td>6 (2.8%)</td>
</tr>
<tr>
<td>Urgent CABG</td>
<td>1 (2.5%)</td>
<td>0</td>
<td>2 (0.9%)</td>
</tr>
<tr>
<td>Death, stent thrombosis</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Death, other</td>
<td>0</td>
<td>1 (0.6%)</td>
<td>2 (0.9%)</td>
</tr>
<tr>
<td>Bleeding</td>
<td>2 (5%)</td>
<td>15 (8.5%)‡</td>
<td>17 (7.9%)</td>
</tr>
<tr>
<td>Tamponade</td>
<td>0</td>
<td>2 (1.2%)</td>
<td>2 (0.9%)</td>
</tr>
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</table>

Group 1, nonanticoagulated; group 2, anticoagulated; n, number of patients; CABG, coronary artery bypass graft.

*p<0.0001, †p<0.0003, ‡p=NS.

canalization. Four of these seven patients had interruption or discontinuation of their antiplatelet therapy for various reasons before the thrombotic event.

One patient underwent urgent bypass surgery directly from the catheterization laboratory for a guiding catheter–induced dissection of the proximal right coronary artery after successful placement of two stents to the mid-right coronary artery. Another patient with subacute closure 10 days after the stenting was recanalized successfully but developed spasm of the distal left anterior descending coronary artery that resolved with intracoronary nitroglycerin. This patient was sent without ischemia to uncomplicated bypass surgery and received an internal mammary artery implant to the left anterior descending coronary artery.

Two patients developed hemorrhagic complications, one with a retroperitoneal bleed requiring transfusion and another with a pseudoaneurysm requiring surgical repair. Occlusive spasm between two stents was seen in one patient in this group and was treated successfully with a third stent.

Group 2: Anticoagulated. The 174 patients in this group each received the articulated stent. There was no case of abrupt closure in this group and only one (0.6%) case of subacute closure after stenting (day 10) despite adequate anticoagulation. This patient had received two stents with 75% overlap and then developed thrombotic occlusion with acute myocardial infarction (creatinine phosphokinase 3,000) at 10 days that was resistant to recanalization. The patient ultimately underwent successful elective bypass surgery.

Nonocclusive thrombotic events occurred in two patients. One developed a brief episode of chest pain at 28 hours after stenting and angiographically demonstrated a small thrombus within the stent, which was treated successfully with intracoronary urokinase (50,000 units). Although there was no further angina, this patient went on to elective bypass surgery for associated left main coronary disease. Another patient who inadvertently had not received dextran before the operation developed a brief episode of angina 1–2 hours after stenting, which resolved after a heparin bolus and nitrates. Immediate angiography revealed minimal nonocclusive thrombus within the stent, which resolved with intracoronary urokinase, intravenous dextran, and repeat dilatation. The patient recovered uneventfully and remains asymptomatic at 3 months of clinical follow-up.

There was one death from an intracranial hemorrhage 8 weeks after successful stenting of a totally occluded circumflex artery (Figures 6a and 6b). Autopsy revealed a patent artery with a thin layer of endothelialized neointimal growth (300–600 μm) overlying the area of stent overlap, which was highly cellular compared with the relatively acellular and thin neointimal layer (<50 μm) at either end of the nonoverlapped stents (Figures 6e and 6f).

There were two cases of tamponade. One occurred 1 month after stenting in a patient in group 2 with uremic pericarditis. Thoracotomy revealed blood in the pericardium, which was treated successfully with pericardectomy. Angiographic follow-up revealed that the stented arterial segment remained widely patent. A second patient developed tamponade acutely as a result of right ventricular perforation with a pacing wire, which was treated successfully with surgery.

Four patients in group 2 developed gastrointestinal bleeding requiring transfusion, eight developed hematoma requiring surgery or transfusion, and two developed pseudoaneurysms for a vascular complication rate of 10 of 174 (5.7%). There were no deaths related to stent thrombosis.

Overall complications. Of the 213 patients in whom stent delivery was successful, seven (3.3%; six in group 1 and one in group 2, p<0.0006) suffered a major complication defined as death, myocardial infarction, or a condition requiring urgent bypass surgery. Other complications such as bleeding and tamponade occurred in 8.9% of these patients (Table 4). Stent embolization occurred in eight (2.5%) of 321 stent delivery attempts and in seven (3%) of 226 patients. One additional patient in whom stent delivery failed experienced successful urgent bypass, and another died after conventional PTCA, yielding an overall major complication rate among patients in whom stent delivery was attempted of 4% (9/226).
Clinical follow-up. A total of 19 (8.9%) patients reported angina in the follow-up period. Thirteen underwent cardiac catheterization, nine of whom had significant narrowing of the stent (≥50%). All of these nine patients required either elective PTCA (four patients) or elective bypass (five patients). One patient underwent emergency bypass for subacute thrombosis, one suffered a fatal hemorrhagic stroke,
one developed asymptomatic stent occlusion, and two were lost to follow-up. Therefore, at the 3-month clinical visit, of the 205 patients that were available for follow-up, 189 (92%) remained asymptomatic.

**Discussion**

The need for endoluminal mechanical support of freshly dilated arteries was recognized by Dotter and Judkins12 over 25 years ago. In 1984 Palmaz et al first introduced the concept of balloon expansion as an alternate mechanism for stent deployment, publishing favorable initial experimental results in 1985.18 Early reports of coronary applications of stents in humans have been less than satisfactory with regard to thrombosis and restenosis.30–32 However, Roubin et al,33 Sigwart et al,34 and Urban et al,35 have reported optimistic early results using stents as a bridge to bypass surgery and in saphenous vein bypass grafts. The current study, however, represents the first large multicenter report in the United States examining the safety and efficacy of elective coronary stenting after PTCA in native coronary arteries.

The obvious cosmetic improvement in vessel appearance seen in this study after stenting (especially in dissected arteries, Figure 2) and the conspicuous
absence of abrupt closure underscores the beneficial effects of mechanically restraining vascular defects after PTCA, as had been suggested by earlier preclinical and clinical studies.24,36 The clinical importance of this finding is enhanced by the observation that the National Heart, Lung, and Blood Institute report11 on 1-year follow-up of the 1985–1986 PTCA registry showed that 20% of all deaths, 40% of all myocardial infarctions, and 25% of all bypass operations occurred in the 6.8% of patients who suffered periprocedural occlusion. Black et al10 reported a relation between dissection and subsequent ischemic outcomes. Both the length of dissection and the presence of extraluminal contrast correlated independently with ischemic complications, which occurred in 11% of the 96% of the 96 patients analyzed. Madison et al9 also found that the incidence of in-hospital ischemic complications increased with the severity of dissection. Thus, the ability to avoid acute closure and to percutaneously repair dissections with stents may favorably influence the overall safety of PTCA by improving short-term clinical outcome.

Although acute closure was absent, subacute closure was common (18%) in this study without anticoagulation but decreased significantly (0.6%, p<0.0001) in those patients who received anticoagulation. The majority of patients in group 1 who developed this complication (four of five) had antiplatelet medications withheld for a variety of reasons. The sensitivity of this device to platelet aggregation was described by Palmaz et al21 in a study that showed increased platelet deposition in stented canine arteries when antiplatelet agents were withheld.21 The one patient in group 2 who suffered late stent occlusion was appropriately anticoagulated but at the time of implantation had approximately 75% overlap of two stents placed in tandem. This high density of metal may predispose to thrombosis early and intimal hyperplasia later (Figures 6a–6f).

In this study, the lower incidence of thrombosis after anticoagulation suggests that this particular stent design may be relatively nonthrombogenic in the immediate postoperative period compared with other stent designs as described in published reports.30–35 In a pilot multicenter trial of a spring-loaded stent (Medinvent, Lausanne, Switzerland), Betrand et al30 reported thrombosis in 4 of 14 patients (28%). Puel et al31 reported thrombosis in 39%, and Sigwart et al37 noted thrombosis using the same stent despite full anticoagulation and intracoronary urokinase, in 16%. In Sigwart’s series, stent diameter influenced thrombosis; it occurred in 3% of patients in whom large diameter stents (4.1±0.8 mm expanded diameter) were placed, compared with 16% of patients who received smaller diameter stents (3.5±0.5 mm). Stents used in our study averaged 2.7±0.5 mm in diameter. Thus, our thrombotic occlusion rate of 0.6% on a similar anticoagulation regimen (group 2) compares favorably with prior series. Thrombosis after 3 months has also been reported by Sigwart et al38 despite anticoagulation and raises the question of incomplete endothelialization with the spring design. Coronary spasm has also been reported with spring devices, the incidence of which appears to diminish with intracoronary nifedipine.38

Patient selection may explain these different clinical outcomes to some degree; only elective PTCA patients with collaterals were stented in this study, whereas 26% of patients in the study of Sigwart et al37 were stented after abrupt closure, in which enhanced thrombogenicity and vasoactivity is common.

Analysis of clinical status up to 3 months after stenting reveals a relatively stable postoperative course: 92% of the patients remained asymptomatic (compared with 6.5% before the operation; p<0.0001), and only 4.3% required elective revascularization with either PTCA or coronary artery bypass graft after hospital discharge. Interpretation of the postoperative status, however, is complicated by the presence of collaterals in the study population, so that completed angiographic follow-up will be required to assess long-term patency.

Limitations

A technical limitation of this and other stents is relative radiolucency resulting from small mass. Poor stent visualization may contribute to imprecise placement, unnecessary overlapping, or excessive gaps between stents when placed in tandem or failure to recognize dislodgement of the stent from the delivery system, resulting in incomplete expansion or embolization of the stent. A second limitation is that without a protective sheath to separate the stent from the vessel wall during delivery, there is a potential risk of intimal damage or snagging of the stent on mural plaques, preventing optimal placement or reliable retrieval. The possibility of passive deformity of the leading edge of the stent during passage and potential snagging has encouraged development of a protective sheath for complex lesions.

Patient entry into the study was also highly selective for relatively proximal lesions in large vessels without tortuosity and, as such, may have introduced bias toward a more favorable outcome. This was offset somewhat by the high incidence of patients in the study with unstable angina (37%) and multiple prior PTCA procedure (69%).

Conclusion

We conclude from this initial study that in a carefully selected group of patients who undergo elective coronary stenting 1) the rigid prototype has limited clinical use due to its inflexibility and propensity for delivery complications, 2) the articulated design is easier to deliver than the prototype, but despite improved operator experience the stent still fails to pass the target lesion in a small number of cases, 3) the risk of acute closure due to thrombosis appears to be very low with this stent, but 4) subacute thrombotic closure of the stent occurs frequently without anticoagulation and may be, in part, related to omission of antiplatelet agents or imprecise place-
FIGURE 6. Angiogram of a patient with two prior angioplasty procedures to the circumflex artery within 2 months. Panel a: Before stent. Panel b: After two stents, articulated (arrows). Panel c: Necropsy specimen harvested 8 weeks after procedure showing stented proximal circumflex artery (solid arrows) patent but with increased neointimal thickness (open arrows) where stents overlap. Panel d: Schematic illustration showing stent overlap seen in panel c. Panel e: Histological short-axis section at the level of stent overlap. Panel f: Proximal to stent overlap. L, lumen; N, neointima; M, media; A, adventitia; P, plaque; *, stent.
ment of multiple stents with a high degree of overlap. The risk period of thrombosis appears to be in the first 2 weeks after placement; thus, we recommend a short course of anticoagulation in addition to antiplatelet agents in all patients.

We are encouraged by these early clinical results and find the procedure to be safe and effective in this carefully selected patient population. Whether this particular stent will solve the greater problem of restenosis can only be answered by analysis of long-term angiographic follow-up, which is forthcoming. We are optimistic that a role may exist for the elective use of coronary stents after angioplasty; however, further studies will be required to better define this role.

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