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# Short- and Long-Term Clinical and Quantitative Angiographic Results With the New, Less Shortening Wallstent for Vessel Reconstruction in Chronic Total Occlusion: A Quantitative Angiographic Study

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***Objectives.*** **This study was designed to examine whether oversized implantation of the new, less shortening Wallstent provides a more favorable long-term clinical and angiographic outcome in chronic total occlusions than does conventional coronary balloon angioplasty.**

***Background.*** **Restenosis and reocclusion remain major limitations of balloon angioplasty for chronic total occlusions. Enforced mechanical remodeling by implantation of the oversized Wallstent may prevent elastic recoil and improve accommodation of intimal hyperplasia.**

***Methods.*** **Lumen dimension was measured by a computer-based quantitative coronary angiography system (CAAS II). These measurements (before and after intervention and at 6-month follow-up) were compared between the groups with Wallstent implantation (20 lesions, 20 patients) and conventional balloon angioplasty (266 lesions, 249 patients) for treatment of chronic total occlusion. Acute gain (minimal lumen diameter after intervention minus that before intervention), late loss (minimal lumen diameter after intervention minus that at follow-up) and net gain (acute gain minus late loss) were examined.**

***Results.*** **Wallstent deployment was successful in all patients. High pressure intra-Wallstent balloon inflation (mean ± SD 14 ± 3 atm) was performed in all lesions. Although vessel size did not differ between the Wallstent and balloon angioplasty groups, acute gain was significantly greater in the Wallstent group (2.96 ± 0.55 vs. 1.61 ± 0.34 mm, $p < 0.0001$). Although late loss was also significantly larger in the Wallstent group (0.81 ± 0.95 vs. 0.43 ± 0.68 mm, $p < 0.05$), net gain was still significantly greater in this group (2.27 ± 1.00 vs. 1.18 ± 0.69 mm, $p < 0.0001$). Angiographic restenosis (≥50% diameter stenosis) occurred at 6 months in 29% of lesions in the Wallstent group and in 45% of those in the balloon angioplasty group ($p = 0.5150$).**

***Conclusions.*** **Implantation of the oversized Wallstent, with full coverage of the lesion length, ensures resetting of the vessel size to its original caliber before disease and allows greater accommodation of intimal hyperplasia and chronic vessel recoil. Wallstent implantation provides a more favorable short- and long-term clinical and angiographic outcome than does conventional balloon angioplasty for chronic total occlusions.**

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The rate of restenosis is significantly higher after successful dilation of total coronary occlusions than after successful dilation of nonoccluded stenoses (1–3). We (3) recently demonstrated, using both a categoric and a continuous approach, that this higher restenosis rate is mainly due to an increased rate of occlusion at follow-up angiography. Multivariate analysis suggested that this increased rate is specifically related to total inflation time and vessel reference diameter after intervention. For several reasons the acute lumen diameter obtained after successful balloon angioplasty is significantly smaller for chronic total occlusions than for nonoccluded stenoses (3). The new less shortening self-expanding Wallstent is characterized by longitudinal flexibility, a protective membrane, a low profile and a customized range of diameters and lengths (4–6). The recent modification in braiding angle and stent strut have resulted in a new device with less shortening on expansion and a concomitant reduction in radial force and improvement in radiopacity (4–6). These modifications may convey a lower restenosis rate because of lower metallic surface per segment and increased feasibility of stent delivery because of higher visibility and less shortening when the stent expands.

We hypothesized that enforced mechanical remodeling by oversized stent implantation after coronary angioplasty may lead to improved local flow dynamics, with a resulting low incidence of acute and subacute occlusion as well as prevention of chronic elastic recoil and improved accommodation of reactive intimal hyperplasia. The new, less shortening Wall-

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stent is ideal for this situation because it is self-expanding, comes in a customized range of long lengths (up to 42 mm) and large diameters (up to 6.0 mm). We examined this strategy of oversized Wallstent deployment in 20 patients after successful laser or balloon angioplasty. Quantitative coronary angiographic analysis was performed before intervention, after balloon angioplasty, after high pressure balloon angioplasty after oversized Wallstent deployment ("Swiss kiss") and at 6-month follow-up. The results were compared with those in patients with total occlusions undergoing successful balloon angioplasty and quantitative angiographic follow-up at 6 months in the same angiographic core laboratory.

## Methods

**Study patients.** *Wallstent implantation group.* To determine the feasibility and efficacy of deployment of the new, less shortening Wallstent in patients with chronic total occlusion, we deployed 25 Wallstents in 20 native coronary artery lesions in 20 patients who had coronary balloon or laser angioplasty of chronic total occlusion >3 months old.

*Balloon angioplasty group.* To provide further insight into the potential short- and long-term mechanisms involved in implantations of the grossly oversized Wallstent, we compared our serial angiographic measurements with those of 266 arteries with total occlusion in 249 patients undergoing successful balloon angioplasty. This study group was selected from 3,582 patients with significant native coronary artery stenosis who were prospectively enrolled in four major restenosis studies and underwent successful coronary angioplasty (7–10). Quantitative angiographic assessment before and after balloon angioplasty and at 6-month follow up was performed with use of the same methodology and at the same angiographic core laboratory (3) for all 266 lesions in 249 patients.

**Laser and balloon angioplasty.** Coronary angioplasty was performed according to standard clinical practice by the femoral approach at the Thoraxcenter (Rotterdam, The Netherlands). Laser angioplasty was applied in patients who had had previously unsuccessful balloon angioplasty. Primary laser angioplasty using a laser wire and catheter was carried out in six patients. Laser wire (0.018-in. [0.046-cm] diameter, Spectranetics) was used to pass into and beyond a lesion with chronic total occlusion when a flexible guide wire (0.014 in. [0.036 cm]) failed to cross the lesion (11,12). Excimer laser system (Spectranetics CVX 300) produced laser fluency with an energy level of 60 mJ/mm$^2$ and a pulse repetition frequency of 25 Hz. The laser wire was advanced ~1 mm/s. After the wire successfully crossed the lesion, a laser catheter (1.4- or 1.7-mm diameter, Spectranetics) was passed over the wire to enlarge the coronary lumen (11,12). After the successful laser procedure, adjunctive balloon angioplasty was carried out. In the remaining 14 patients balloon angioplasty was performed after successful crossing with 0.014-in. guide wire. During the primary balloon angioplasty the balloon diameter was 2.67 ± 0.66 mm and the maximal inflation pressure was 10.3 ± 3.0 atm.

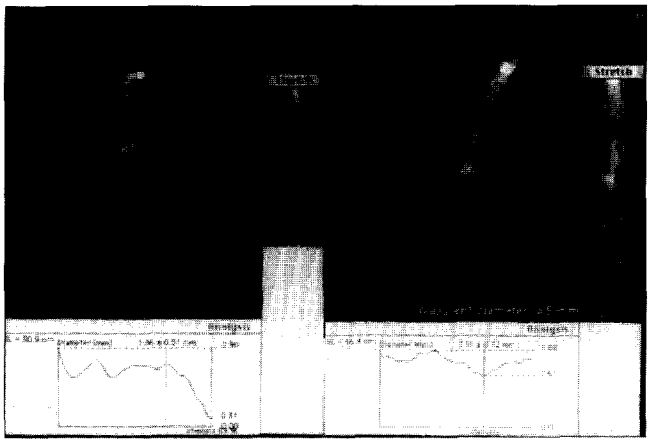

**Figure 1. Left panel,** Angiogram showing total occlusion of a mid-right coronary artery and a maximal vessel diameter of 2.90 mm in the proximal segment. A Wallstent (diameter 4.5 mm, length 35 mm) 1.60 mm larger than the maximal vessel diameter was deployed (**right panel**). Minimal lumen diameter increased from 0 to 2.61 mm, and Thrombolysis in Myocardial Infarction (TIMI) grade 3 flow was restored.

**Wallstent implantation.** Intracoronary ultrasound studies (13–16) have reported that atherosclerotic plaque is commonly observed in angiographically normal proximal reference segments in patients with significant coronary stenosis. We therefore used the maximal vessel diameter, which may be closer to the original vessel diameter in the nondiseased condition than is the interpolated reference diameter traditionally used for stent sizing. After determination of the maximal vessel diameter on the diameter function of the on-line quantitative Coronary Angiographic Analysis System (CAAS II), a Wallstent with a nominal diameter 1.5 mm greater than the maximal vessel diameter and nominal length 5 to 10 mm longer than the lesion length was selected (Fig. 1). Of the 25 stents used in 20 lesions, 1 had a diameter of 4 mm, 2 of 4.5 mm, 6 of 5 mm, 9 of 5.5 mm and 7 of 6 mm. Eleven of the 25 stents had a length of 23 to 28 mm, 8 of 35 mm and 6 of 42 mm. Fifteen patients received one Wallstent and the remaining five patients received two Wallstents. After delivery of the stent, high pressure inflations ("Swiss kiss", 14.0 ± 3.3 atm) using balloon diameters of 3.9 ± 0.7 mm to optimize stent expansion were performed in all 20 patients.

**Anticoagulant therapy.** Patients were given an intravenous bolus dose of 10,000 IU of heparin, and subsequently 5,000 IU at the beginning of the intervention, as required to maintain the activated clotting time >300 s throughout the procedure. In this early experience a standardized postintervention anticoagulant regimen was used (17,18): One hour after removal of the femoral sheath, a heparin intravenous infusion was begun to maintain activated partial thromboplastin time between 70 and 90 s until oral anticoagulant therapy (warfarin sodium [Coumadin]) had achieved a prothrombin time international normalized ratio of 2.5 to 3.5. Coumadin was prescribed for 3 months after stent

implantation and aspirin indefinitely (17,18). Ticlopidine was not used.

**Study end points and definitions.** Procedural success was defined as technically successful deployment of the stent in the absence of any adverse cardiac events, defined as acute or subacute stent thrombosis, repeat intervention, coronary artery bypass surgery, myocardial infarction or death. Angiographic success was defined as a <30% residual diameter stenosis after final deployment of the stent. The primary clinical end point of the study was the occurrence of any adverse cardiac event. Subacute thrombosis was defined as a clinical event leading to cardiac catheterization that identified stent thrombosis within 14 days of stent deployment. Angiographic restenosis was defined as lumen narrowing ≥50% diameter stenosis at follow-up. Long-term clinical outcome included all cardiovascular events occurring within 6 months of stent deployment.

**Quantitative coronary angiographic analysis.** The new version of the computer-based CAAS II system (19) was used to perform on-line quantitative analysis (for immediate guidance of stent sizing in the catheterization laboratory) and the subsequent off-line cine film analysis. In the CAAS analysis, which has previously been described elsewhere (20–25), the entire 18- × 24-mm cine frame is digitized at a resolution of 1,329 × 1,772 pixels. Correction for pincushion distortion is performed before analysis. Boundaries of a selected coronary segment are detected automatically. The absolute diameter of the stenosis (in mm) is determined by using the guiding catheter as a scaling device (26). To standardize the method of analysis of the initial and follow-up angiograms, the following measures were taken: All study frames selected for analysis were end-diastolic to minimize motion artifact; arterial segments were measured between the same identifiable branch points after administration of isosorbide dinitrate (27–30).

**Quantitative angiographic variables.** Acute gain and late loss represent the improvement in minimal lumen diameter achieved at intervention (minimal lumen diameter after stenting minus that before stenting) and the changes at follow-up (minimal lumen diameter after stenting minus that at follow-up), respectively. Net gain (gain minus loss) was examined. Vessel size was defined as a interpolated reference diameter after balloon angioplasty (31). Because the algorithm cannot measure total occlusions, a value of 0 mm was imputed for the minimal lumen diameter, and the reference diameter after balloon angioplasty was substituted for that before intervention. Net gain index (net gain divided by the reference diameter before angioplasty), relative loss (loss divided by the reference diameter before intervention) and loss index (loss divided by gain) were studied.

**Statistical analysis.** Data were analyzed by using the SAS statistical software package. Categoric variables are presented as absolute numbers (%). Continuous variables are expressed as mean value ± 1 SD. Differences between groups were evaluated by using adjusted chi-square tests for categoric variables and Student *t* tests for continuous variables. A p value < 0.05 was considered significant.

**Table 1.** Clinical and Angiographic Characteristics of the Patients

| | Wallstent Implantation Group (n = 20 patients) | Balloon Angioplasty Group (n = 249 patients) | p Value |
|---|---|---|---|
| Male | 95.0% | 85.1% | 0.3765 |
| Age (yr) | 55.9 ± 9.3 | 54.4 ± 9.6 | 0.5011 |
| Prior myocardial infarction | 50.0% | 54.2% | 0.8958 |
| Prior successful balloon angioplasty | 5.0% | 3.6% | 0.5445 |
| Prior coronary bypass surgery | 10.0% | 1.6% | 0.0971 |
| Coronary risk factors | | | |
| Hypercholesterolemia | 30.0% | 33.3% | 0.9538 |
| Systemic hypertension | 30.0% | 30.1% | 0.8087 |
| Cigarettes (ever smoked) | 65.0% | 73.1% | 0.6034 |
| Diabetes | 10.0% | 10.8% | 0.7966 |
| CCS angina class | | | |
| None | 5.0% | 6.0% | 0.7603 |
| I | 10.0% | 10.0% | 0.7032 |
| II | 35.0% | 33.7% | 0.8961 |
| III | 30.0% | 28.9% | 0.4736 |
| IV | 20.0% | 21.3% | 0.8815 |
| No. of diseased vessels | | | |
| 1 | 60.0% | 61.0% | 0.8838 |
| 2 | 30.0% | 34.5% | 0.8676 |
| 3 | 10.0% | 3.6% | 0.4233 |
| Lesion location | | | |
| RCA | 70.0% | 33.7% | 0.0026 |
| LAD | 30.0% | 39.4% | 0.5564 |
| LCx | 0 | 26.9% | 0.0160 |
| TIMI flow before intervention | | | |
| TIMI 0 | 75.0% | 41.0% | 0.0063 |
| TIMI 1 | 25.0% | 59.0% | 0.0063 |

Data presented are percent of patients or mean value ± SD. CCS = Canadian Cardiovascular Society; TIMI = Thrombolysis in Myocardial Infarction grade flow (32).

## Results

**Baseline clinical and angiographic characteristics in the Wallstent and balloon angioplasty groups (Table 1).** No difference was found between the Wallstent implantation and balloon angioplasty groups in gender, age, previous myocardial infarction, previous successful balloon angioplasty, previous coronary bypass surgery, coronary risk factors, angina class or number of diseased vessels. The incidence of absolute total occlusions (Thrombolysis in Myocardial Infarction [TIMI] grade 0 [32]) was significantly higher in the Wallstent group than in the balloon angioplasty group. The Wallstent was predominantly deployed in the right coronary artery, which has few significant side branches at risk of occlusion by full coverage of a long lesion using the Wallstent (4).

**Clinical outcome.** Delivery of all 25 Wallstents was possible, and no cardiac event occurred during the procedure.

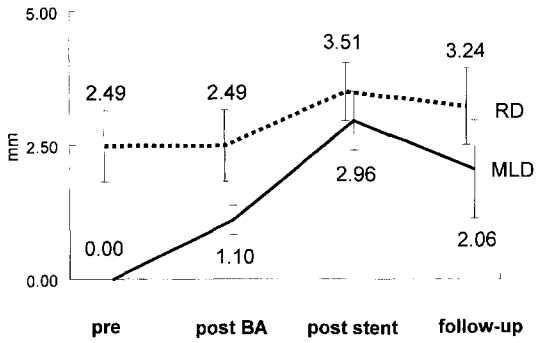


**Figure 2.** Changes in minimal lumen diameter (MLD) and reference diameter (RD) in 20 lesions from before (pre) intervention through the periods after balloon angioplasty (post BA) and after stent implantation (post stent) to follow-up. Minimal lumen diameter improved markedly after Wallstent implantation and the performance of a Swiss Kiss.

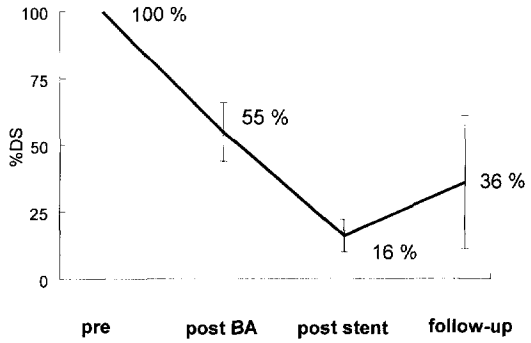


**Figure 4.** Changes in percent diameter stenosis (% DS) in 20 lesions from before intervention (pre) through after balloon angioplasty (post BA) and after stent implantation (post stent) to follow-up. There was a marked decrease in residual stenosis after Wallstent implantation and the performance of a "Swiss kiss".

Angiographic success (<30% diameter stenosis) was achieved in all patients with Wallstent implantation. One patient sustained a subacute occlusion on day 1 associated with a non-Q wave myocardial infarction (creatine kinase 228 IU/liter) and was immediately treated by balloon angioplasty, which promptly restored TIMI grade 3 flow. Of the 19 patients in the Wallstent group eligible for 6-month angiographic follow-up, 2 asymptomatic patients declined restudy. Thus, the angiographic follow-up rate of the Wallstent group was 89%, a rate comparable to the 86% rate in the control balloon angioplasty group (3). Angiographic restenosis (≥50% diameter stenosis) at 6 months occurred in 5 (29%) of 17 lesions in the Wallstent group and in 119 (45%) of 266 lesions in the balloon angioplasty group. The overall event-free survival rate at 6-month follow-up was 75% (15 of 20 patients) in the Wallstent group and 71% (195 of 249 patients) in the balloon angioplasty group.

**Quantitative angiographic analysis in the Wallstent group.** The average nominal diameter of the Wallstents used was 1.82 ± 0.83 mm greater than the maximal vessel diameter and 11.0 ± 7.3 mm longer than the lesion length. Minimal lumen diameter increased from 0 mm before intervention to 1.10 ± 0.28 mm after balloon angioplasty (Fig. 2). After stent implantation, high pressure balloon dilation of 14.0 ± 3.3 atm ("Swiss kiss") using balloons of 3.9 ± 0.7-mm diameter was performed in all lesions. Implantation of the Wallstent further increased the minimal lumen diameter to 2.96 ± 0.55 mm (Fig. 2). At 6-month follow-up, minimal lumen diameter decreased to 2.06 ± 0.92 mm. Figure 3 provides an example of the serial angiographic outcome in an individual patient. Figure 4 shows percent diameter changes from the period before intervention through the period after stent implantation to 6-month follow-up.

**Quantitative angiographic comparison with the group undergoing balloon angioplasty (Table 2).** No difference was found in vessel size (interpolated reference diameter before intervention) between the Wallstent and balloon angioplasty groups. There was a significantly greater reference diameter after intervention in the Wallstent group, and this difference remained at follow-up. The minimal lumen diameter increased substantially more after Wallstent implantation, as reflected in the substantially lower percent residual stenosis. At follow-up, although the absolute loss was significantly higher in the Wallstent group, the greater initial gain allowed improved accommodation of the intimal hyperplasia, and both the minimal lumen diameter and percent diameter stenosis at follow-up were significantly lower in the Wallstent group. Although the restenosis rate using the categoric approach


**Figure 3.** Coronary angiograms of the right coronary artery in a patient with total occlusion before balloon angioplasty (**A**). After balloon angioplasty a Wallstent (nominal diameter 6.0 mm, length 42 mm) was deployed. The radiopaque stent delivery system and the markers can be seen during deployment (**B**). After Wallstent deployment, minimal lumen diameter was 3.06 mm in association with a 15% residual diameter stenosis (**C**). Follow-up angiography at 6 months revealed a minimal lumen diameter of 2.16 mm in association with a 35% diameter stenosis (**D**).

**Table 2.** Quantitative Angiographic Analysis Results in the Wallstent and Balloon Angioplasty Groups

| | Wallstent Implantation Group (n = 20 lesions) | Balloon Angioplasty Group (n = 266 lesions) | p Value |
|---|---|---|---|
| Reference diameter (mm) | | | |
| Before stent implantation | 2.49 ± 0.67 | 2.46 ± 0.49 | 0.7976 |
| After intervention | 3.51 ± 0.55 | 2.46 ± 0.49 | < 0.0001 |
| At follow-up | 3.24 ± 0.72 | 2.60 ± 0.55 | < 0.0001 |
| Minimal lumen diameter (mm) | | | |
| Before intervention | 0 | 0 | — |
| After intervention | 2.96 ± 0.55 | 1.61 ± 0.34 | < 0.0001 |
| At follow-up | 2.06 ± 0.92 | 1.18 ± 0.69 | < 0.0001 |
| Differences in minimal lumen diameter (mm) | | | |
| Absolute gain | 2.96 ± 0.55 | 1.61 ± 0.34 | < 0.0001 |
| Relative gain | 1.19 ± 0.30 | 0.66 ± 0.09 | < 0.0001 |
| Absolute loss | 0.81 ± 0.95 | 0.43 ± 0.68 | 0.0201 |
| Relative loss | 0.33 ± 0.39 | 0.17 ± 0.28 | 0.0175 |
| Absolute net gain | 2.27 ± 1.00 | 1.18 ± 0.69 | < 0.0001 |
| Net gain index | 0.92 ± 0.40 | 0.48 ± 0.28 | < 0.0001 |
| Loss index | 0.27 ± 0.31 | 0.26 ± 0.43 | 0.9189 |
| Percent diameter stenosis (% DS) | | | |
| Before intervention | 100 | 100 | — |
| After intervention | 15.85 ± 6.33 | 34.16 ± 8.46 | < 0.0001 |
| At follow-up | 36.38 ± 24.78 | 54.08 ± 25.67 | 0.0031 |
| % DS at follow-up ≥50% | 29.41% | 44.74% | 0.5150 |

Data presented are mean value ± SD or percent of lesions.

tended to be lower in the Wallstent group, this difference did not achieve statistical significance.

## Discussion

Our study showed that implantation of the grossly oversized Wallstent can be safely and successfully performed in patients with total coronary occlusion. Furthermore, after successful delivery of the stent, angiographic success, as defined by <30% residual diameter stenosis, can be achieved in all cases. Despite the propensity to reocclusion of lesions in this group, Wallstent deployment resulted in a low risk of acute or subacute stent thrombosis and a low rate of restenosis and reocclusion at 6-month follow-up. Thus, our policy of oversized Wallstent implantation resulted in a resetting of vessel size and a tendency toward a lower restenosis rate than that of occlusions undergoing standard balloon angioplasty.

**Reasons for high delivery success rate and safety.** The high delivery success rate may be explained by the low profile (1.57 mm) and longitudinal flexibility of the Wallstent, which allow successful negotiation of tortuous vessels. Furthermore, the protective rolling membrane of the Wallstent prevents migration of the stent during negotiation of the target lesion, and the fine mesh structure of the device may prevent distal embolization of friable tissue from the recanalized total occlusion after successful laser or balloon angioplasty. Although a previous study (33) of angioplasty with deliberately oversized balloons in coronary stenoses suggested that that procedure may result in a higher rate of acute complications, the self-expanding nature of the Wallstent and its fine mesh structure are probably also responsible (by providing support and scaffolding for the vessel wall) for the safe deployment of such grossly oversized stents in total occlusions.

**Comparison with balloon angioplasty group.** By comparing our results with those of a group of total occlusions undergoing coronary balloon angioplasty and 6-month quantitative angiographic follow-up in the same angiographic core laboratory, we were able to demonstrate that our policy of gross oversizing does indeed result in resetting of the vessel size to what is assumed to be its original state before disease. Furthermore, this oversizing results in a minimal lumen diameter after implantation that is significantly larger than the balloon angioplasty group reference diameter. Thus, despite the greater absolute and relative loss during follow-up of the Wallstent, the minimal lumen diameter at follow-up was significantly higher and the percent stenosis lower in this group. Although the resulting reduction in the categoric restenosis rate did not achieve statistical significance, this may have been due to the small number of lesions in our Wallstent group. The loss index was almost identical in both groups, ~0.26 compared to a reported loss index of 0.50 for nonoccluded stenoses (34,35), suggesting that although the vessel reaction is similar after either balloon dilation or grossly oversized stent implantation, the relative fibroproliferative response in total occlusions is only half that seen in nonoccluded stenoses (34). This observation may represent significant differences in the underlying pathologic substrate, with total occlusions having less normal vessel wall and vessel media with which to mount a substantial fibroproliferative response (36,37). Alternatively, differences in elastin content may result in less chronic recoil and vessel remodeling in successfully dilated occlusions (36,37).

**Comparison with other stents for the treatment of total occlusions.** Previous studies (38–41) have also examined stent implantation for the treatment of total coronary occlusions as elective therapy or as therapy for suboptimal results or for acute or threatened vessel closure. Depending on the indication and type of stent used, follow-up angiographic restenosis rates have varied from 24% to 57%; the highest rate was obtained with the Gianturco-Roubin stent used in bailout situations. Our results compare favorably with these previously published data, and we believe that the Wallstent has some additional advantages over other stent designs in total coronary occlusions. These include the customized length of up to 42 mm, which enables full coverage of the totally occluded lesion and avoids multiple stenting, which is more time-consuming and is also more likely to result in subacute thrombosis (42). The larger expanded diameter of up to 6.0 mm also allows implantation of the grossly oversized Wallstent and resetting of the previously occluded vessel to its original condition before disease. Additionally, the high flexibility of the Wallstent allows more natural bending and tortuosity, factors that may be more favorable to dynamic

coronary flow. The self-expanding characteristics of the stent may play a role in preserving the large initial gain during follow-up by exerting a persisting strong radial force.

**Limitations of study.** Our study has several limitations: 1) Because our study numbers are small, the data need to be confirmed by larger multicenter studies. 2) We used an unmatched control group of lesions undergoing successful balloon angioplasty and quantitative angiographic follow-up for comparison. Differences in study patients and procedural characteristics between the Wallstent and balloon angioplasty groups may have exerted some influence on clinical and angiographic outcome. For example, there are significant differences between the left anterior descending and right coronary arteries in local flow dynamics, vessel geometry, external compressive forces (43) and propensity to restenosis (44). The predominance of right coronary artery lesions in our stent group may have had a substantial influence on the subsequent risk of occlusion and restenosis. Although there was a greater incidence of TIMI grade 0 lesions in the stent group, there is no evidence to suggest that these lesions are either more or less prone to restenosis than TIMI grade 1 lesions (3). Similarly, although patients in the Wallstent group received anticoagulant therapy for 3 months after intervention, there is no evidence to suggest that this treatment may have led to a reduction in restenosis (45).

**Clinical implications.** Recanalization of total occlusions remains limited by a higher restenosis rate than that seen after successful dilation of nonocclusive stenoses. Our study suggests not only that implantation of the grossly oversized new Wallstent is feasible and safe but that the resulting mechanical remodeling of the vessel can improve local flow dynamics with a resulting low incidence of subacute occlusion and prevention of late elastic recoil enabling increased accommodation of late lumen loss during follow-up. Our results need to be confirmed in larger, multicenter, randomized studies but suggest that a policy of implantation of the grossly oversized Wallstent in patients with total occlusion will result in a lower angiographic restenosis rate and improved clinical outcome. Adoption of a policy of gross oversizing with more rigid, balloon-expandable stents, such as the Palmaz-Schatz stent, may be entirely inappropriate and unsafe. Thus, the implications of our study should be limited to the new self-expanding, less shortening Wallstent. Finally, because the Wallstent is a fine mesh stent, performing angioplasty to a side branch through it is technically very difficult. Furthermore, even if angioplasty were performed for disease in a side branch before stent deployment in the main vessel, difficulties would be encountered if restenosis occurred. Additionally, a certain amount of intimal hyperplasia is anticipated inside the Wallstent; thus, if a side branch has a significant untreated narrowing at its origin before stent implantation in the main vessel, there is a significant risk of disease progression during follow-up. Because of these considerations the Wallstent was used predominantly in the right coronary artery in this and previous studies (4), and its use will be more limited in the left coronary system.

**Conclusions.** The safety and feasibility of implantation of the oversized Wallstent for the treatment of chronic total coronary occlusions were demonstrated. Oversized Wallstent implantation, with full coverage of the lesion length, ensures resetting of the vessel size to its original caliber before disease in patients with chronic total occlusion and allows greater accommodation of intimal hyperplasia and chronic vessel recoil. In comparison with conventional balloon angioplasty, oversized Wallstent implantation conveys a more favorable short- and long-term clinical and angiographic outcome.

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