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Comparison of In Vivo Acute Stent Recoil Between the Bioabsorbable Everolimus-Eluting Coronary Stent and the Everolimus-Eluting Cobalt Chromium Coronary Stent: Insights From the ABSORB and SPIRIT Trials

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Objectives: This study sought to evaluate and compare in vivo acute stent recoil of a novel bioabsorbable stent and a metallic stent. Background: The bioabsorbable everolimus-eluting coronary stent (BVS) is composed of a poly-L-lactic acid backbone, coated with a bioabsorbable polymer containing the antiproliferative drug, everolimus, and expected to be totally metabolized and absorbed in the human body. Because the BVS is made from polymer, it may have more acute recoil than metallic stents in vivo. Methods: A total of 54 patients, who underwent elective stent implantation for single de novo native coronary artery lesions, were enrolled: 27 patients treated with the BVS and 27 patients treated with the everolimus-eluting cobalt chromium stent (EES). Acute absolute recoil, assessed by quantitative coronary angiography, was defined as the difference between mean diameter of the last inflated balloon at the highest pressure (*X*) and mean lumen diameter of the stent immediately after the last balloon deflation (*Y*). Acute percent recoil was defined as (*X* – *Y*)/*X* and expressed as a percentage. Results: Acute absolute recoil of the BVS and EES was 0.20 ± 0.21 mm and 0.13 ± 0.21 mm, respectively (*P* = 0.32). Acute percent recoil was 6.9% ± 7.0% in the BVS group and 4.3% ± 7.1% in the EES group (*P* = 0.25). Conclusions: In vivo acute stent recoil of the BVS is slightly larger but insignificantly different from that of the EES, implying that the BVS may have good radial strength similar to the metallic stent. © 2007 Wiley-Liss, Inc.

Key words: bioabsorbable; coronary artery disease; recoil; stents

INTRODUCTION

Coronary stents have been used as standard mechanical devices for percutaneous coronary intervention (PCI) in the treatment of patients with coronary artery disease (CAD) [1]. They provide vessel wall scaffolding and prevent early elastic recoil and restenosis, which are major limitations of balloon angioplasty. Consequently, the use of coronary stents achieves high success rates of PCI and improves the outcome of CAD patients. However, because of the permanent nature of metallic stents, their presence on the intimal surface of a coronary artery poses risks associated with a continuous interaction between the metal and the surrounding tissue [2]. This can lead to long-term endothelial dysfunction or chronic inflammation, and may result in many potential concerns, such as in-stent neointimal hyperplasia and thrombogenesis. The clinical requirement of stents for vessel scaffolding is tempo-

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rary and limited to the time of the revascularization and, shortly thereafter, until vascular healing and re-endothelialization within the stented coronary segment have taken place. Beyond this period, the advantage of metallic stents diminishes. Indeed, when compared with bare metal stents (BMS), drug-eluting stents (DES) significantly reduce coronary restenosis by applying an antiproliferative drug to inhibit the intimal hyperplastic response [3,4]. However, once the drug is eluted from DES, they behave like metallic stents. In addition, as the drug itself inhibits endothelial function [5] or normal vascular healing [6] or both, prolonged antiplatelet therapy is required to prevent stent thrombosis in patients treated with DES [7,8].

In terms of the short-term need for vessel scaffolding and avoidance of the potential long-term complications of metallic stents, bioabsorbable polymer stents appear to be an ideal alternative candidate material. Further, they can also be used as a vehicle for drug delivery to target lesions. Conceptually, once they are fully absorbed, only the healed vessels are left behind with no residual prosthesis and, therefore, no potential interactions with the coronary artery. Accordingly, long-term antiplatelet therapy may not be warranted. However, in quest for preventing acute vessel recoil, there has been concern that polymer stents may not be efficacious due to their intrinsic characteristics when compared with metallic stents.

The bioabsorbable everolimus-eluting coronary stent (BVS: developed by Bioabsorbable Vascular Solutions, Mountain View, CA) is composed of a poly-L-lactic acid (PLLA) backbone, coated with a bioabsorbable polymer containing the antiproliferative drug everolimus (Certican®, Novartis Pharmaceuticals Corporation, Basel, Switzerland). The ongoing first-in-man trial (the ABSORB trial) assesses its safety and feasibility in patients with CAD. In the present study, we evaluated acute stent recoil of the BVS in the ABSORB trial. In addition, using the SPIRIT clinical trials as a control group, we compared the acute stent recoil of the BVS and the XIENCE V everolimus-eluting cobalt chromium stent (EES: manufactured by Advanced Cardiovascular Systems, Santa Clara, CA).

METHODS

Study Population

The ABSORB trial is a prospective, open-labeled, multicenter (six clinical sites), first-in-man clinical investigation of the BVS in patients with single de novo native coronary artery lesions. It was approved by the ethics committee at each participating institution, and all patients gave written informed consent. Patients were eligible for the study if they were aged above 18 years, with a diagnosis of stable or unstable angina, or silent ischemia. Target lesions were selected that could be covered with a single stent of 3.0 × 12 mm^2 or 3.0 × 18 mm (i.e. 3.0 mm in diameter by visual estimation, less than 8 mm or 14 mm in length) and a stenosis of between 50% and 99% of luminal diameter with a Thrombolysis in Myocardial Infarction flow grade of 1 or more. Patients were ineligible if they had any of the following: evolving myocardial infarction; left main coronary artery stenosis; an ostial lesion; lesion located within 2 mm of a bifurcation; lesion with moderate-to-heavy calcification by visual assessment; angiographically visible thrombus within the target lesion; a left ventricular ejection fraction of less than 30%; candidate for heart transplant; known hypersensitivity or contraindication to aspirin, heparin, clopidogrel, everolimus, PLLA, or contrast sensitivity that could not be adequately premedicated.

In order to compare the acute stent recoil of BVS and metallic stents, we chose patients enrolled in the recently completed SPIRIT trials as the control group. The SPIRIT trials are planned to assess the safety and efficacy of the EES in patients with CAD. To date, short-term follow-up results of the SPIRIT FIRST trial [9,10] and the SPIRIT II trial [11] have been reported. Both trials were prospective, multicenter, single-blinded, randomized-controlled clinical investigations in patients with the diagnosis of stable or unstable angina, or silent ischemia and compared EES with BMS (SPIRIT FIRST trial) or paclitaxel-eluting stents (SPIRIT II trial). The study protocol of these two trials has been reported previously [9,11]. Briefly, the patients of the SPIRIT FIRST trial had a single de novo native coronary stenosis of less than 12 mm lesion length, covered by a single stent of 3.0 × 18 mm, more than 50% diameter stenosis, and a vessel reference diameter of 3.0 mm, as assessed by online quantitative coronary angiography (QCA). In the SPIRIT II trial, eligibility criteria were the presence of maximum two de novo native coronary lesions, each located in a different major epicardial coronary vessel. Stent sizes available were 2.5, 3.0, 3.5, or 4.0 mm in diameter and 8, 18, or 28 mm in length. Target lesions were less than 28 mm length, covered by a single stent or two overlapping stents, more than 50% diameter stenosis, with the vessel reference diameter ranging from 2.5 to 4.25 mm as assessed by visual estimation. Exclusion criteria of these two SPIRIT trials were similar to those of the ABSORB trial.

Careful considerations were taken to select the control group to adjust for target lesion characteristics, since several differences in inclusion criteria existed and different stent sizes were available among these three trials. Finally, as the control group, we selected consecutive patients who

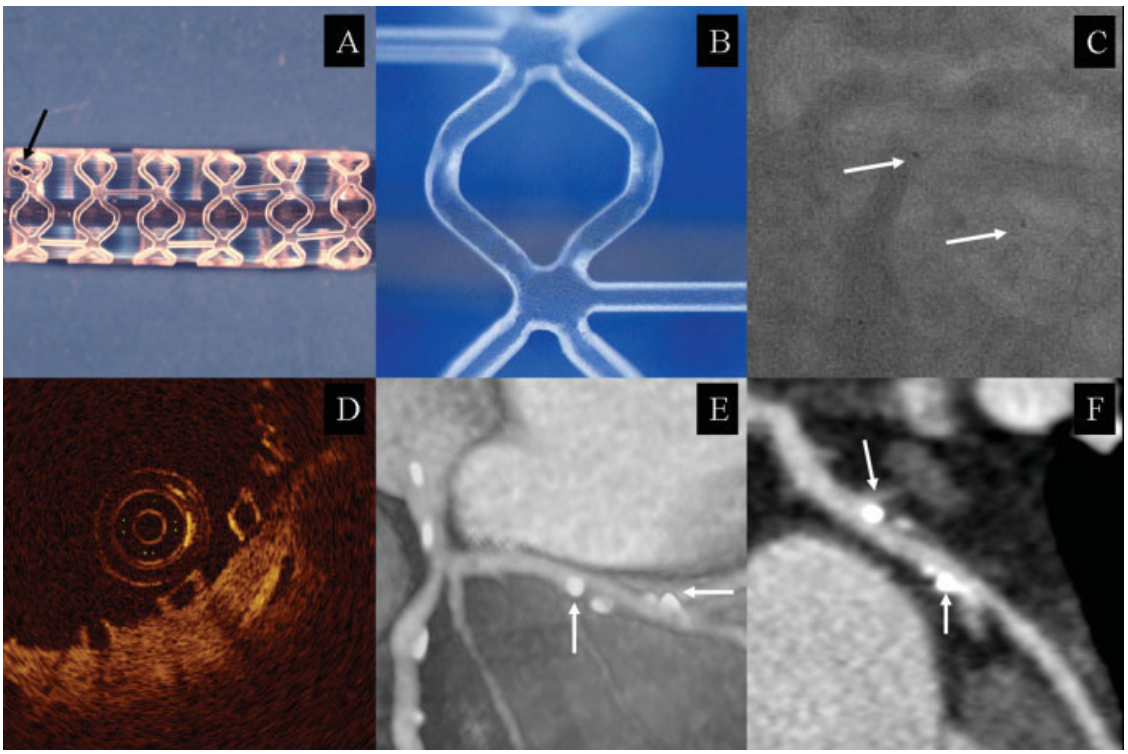

Fig. 1. Bioabsorbable everolimus-eluting coronary stent (BVS). Panel A shows an overview of the stent. The black arrow indicates a radio-opaque platinum marker on the surface of the stent. Panel B is the magnified image of the stent. The stent body is transparent. Two radio-opaque markers (white arrows) on both ends of the stent are easily detected by the fluoroscopy (Panel C), although the stent body is radiolucent. Optical coherence tomography can clearly indicate stent struts as a unique box appearance (Panel D). The stent strut thickness is 0.150 mm. In Panel E and F, multislice computed tomography demonstrates that two radio-opaque markers (white arrows) are clearly visible and the stent body is invisible. [Color figure can be viewed in the online issue, which is available at www.interscience.wiley.com.]

received a single 3.0 × 18 mm EES for a single de novo lesion from the SPIRIT FIRST and II trials.

Description of the Stent

The BVS is comprised of four main components: the polymer stent backbone, the polymer drug reservoir, the antiproliferative drug everolimus, and the delivery system. The polymer stent is balloon-expandable and is composed of a high-molecular-weight PLLA backbone, with serpentine rings connected by links (Fig. 1A and B). The stent body is coated with a matrix of everolimus and poly-D,L-lactic acid (PDLLA) in a 1:1 ratio. PLLA and PDLLA are fully metabolized and totally absorbed in the human body. The BVS is laser-cut from an extruded tube of the PLLA and has two radio-opaque platinum markers on both ends of its surface, to facilitate the identification of the prosthesis (Fig. 1C). Two stent sizes are available: 3.0 × 12 mm or 3.0 × 18 mm. The thickness of the stent struts is 0.150 mm (Fig. 1D). The stent itself is mounted on the VISION RX balloon catheter, which has two radio-opaque balloon markers, reflecting the expanded stent length. These markers aid in positioning the stent fluoroscopically.

The EES has been described in detail previously [9]. Briefly, the EES is composed of the MULTI-LINK VISION® Stent (Abbott Vascular, Santa Clara, CA), which is a balloon-expandable stent with serpentine rings connected by links fabricated from a single piece of medical grade L-605 cobalt chromium alloy, coated with a durable polymer containing everolimus. The morphological design of the EES is similar to that of the BVS. The thickness of the strut is 0.081 mm. The stent is mounted on the MULTILINK VISION® balloon catheter, which is identical to the BVS delivery balloon catheter.

Study Procedure

All procedures were performed electively. Target lesions were treated using standard interventional techniques, with mandatory predilatation and stent deployment at a pressure not exceeding the rated burst pressure (16 atm). Postdilatation with a balloon shorter than the implanted stent was allowed at operator discretion if an optimal angiographic result was not

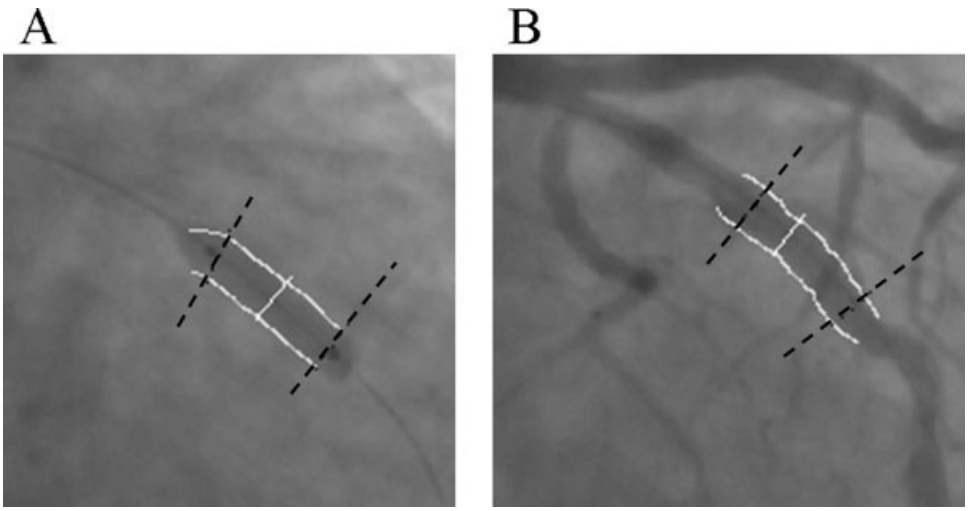

Fig. 2. Methodology of acute stent recoil assessment when only the stent delivery balloon was used for stent expansion. Image A is of complete expansion of the stent delivery balloon. Image B is immediately after balloon deflation. In Image A, analysis is performed between balloon markers (between dotted lines; Segment A). In Image B, analysis is performed within the stent markers (between dotted lines; Segment B). These two images are analyzed in the same angiographic projection, so that segments A and B are well-matched. In this case, the mean diameter of segments A and B are 3.10 and 2.83 mm, respectively. This corresponds to acute recoil of 0.27 mm or 8.7%. White solid lines indicate the minimum diameter of the balloon or minimum lumen diameter within the analyzed segment.

obtained immediately after stent deployment. Bailout stenting for edge dissection was permitted. During PCI, intravenous boluses of heparin were administered according to local practice. Treatment with aspirin was started at least 24 hr before the procedure, and continued throughout the length of clinical investigation in the ABSORB trial and for at least 1 year in the SPIRIT trials. A loading dose of 300 mg of clopidogrel was administered before the procedure, followed by 75 mg daily for a minimum of 6 months in the ABSORB and SPIRIT II trials and for 3 months in the SPIRIT FIRST trial.

Quantitative Coronary Angiography Analysis

QCA was performed using the CAAS II analysis system (Pie Medical BV, Maastricht, the Netherlands). For each patient, the stented segment and the peri-stent segment (defined by a length of 5 mm proximal and distal to the stent edge) were analyzed. The following QCA parameters were computed: minimal luminal diameter (MLD), reference vessel diameter, and percent diameter stenosis. In addition to the baseline and post-PCI images, two images were analyzed for acute stent recoil assessment in this study. One was an image of complete expansion of the last balloon (either the stent delivery balloon or the postdilatation balloon) at the highest pressure (Image A, Figs. 2A and 3A). The other was an image immediately after the last balloon deflation (Image B, Figs. 2B and 3B). These two images were analyzed in the same angiographic projection. The time interval between Images A and B was usually less than 1 min. When the stent delivery balloon was used for stent expansion, QCA measurement was performed between the markers of the stent delivery balloon (Segment A) in Image A and within the deployed stent markers (Segment B) in Image B. In case a postdilatation balloon was used during the procedure, the measurement was performed between markers of the postdilatation balloon in Image A (Segment C) and within the segment area in Image B, where the postdilatation balloon was placed and inflated (Segment D). When bailout stenting was performed and a nonstudy stent overlapped with the study stent, only the study stent segment was analyzed.

Acute Stent Recoil Assessment

Acute stent recoil was calculated as follows [12,13]: (1) When the stent delivery balloon was used for stent expansion, acute absolute stent recoil was defined as the difference between mean diameter of the stent delivery balloon at the highest pressure in the Segment A (X) and mean luminal diameter in the Segment B (Y). Acute percent stent recoil was defined as $(X - Y)/X$ and expressed as a percentage. (2) In case a postdilatation balloon was used in the procedure, acute absolute recoil was defined as the difference between mean diameter of the postdilatation balloon at the highest pressure in Segment C (X') and mean luminal diameter in Segment D (Y'). Acute percent recoil was defined as $(X' - Y')/X'$ and expressed as a percentage.

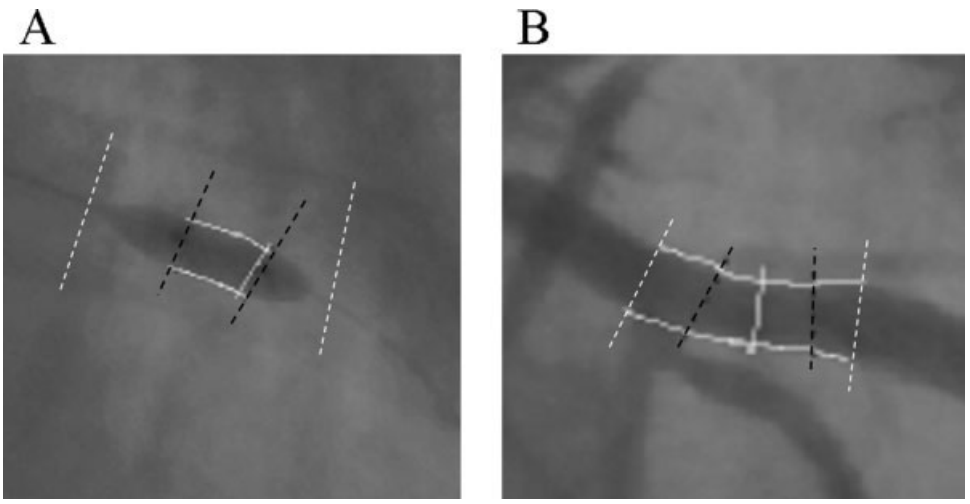

Fig. 3. Methodology of acute stent recoil assessment when a postdilatation balloon was used during the procedure. Image A is of complete expansion of the postdilatation balloon. Image B is immediately after balloon deflation. In the Image A, analysis is performed between balloon markers (between black dotted lines; Segment C). In the Image B, analysis is performed within the stent in the same segment where the postdilatation balloon was placed and inflated (between black dotted lines; Segment D). These two images are analyzed in the same angiographic projection, so that segments C and D are well-matched. In this case, the mean diameter of segments C and D are 3.33 and 3.15 mm, respectively. This corresponds to acute recoil of 0.18 mm or 5.4%. White solid lines indicate the minimum diameter of the balloon or minimum lumen diameter within the analyzed segment. White dotted lines indicate the stented segment.

Statistical Analysis

The analysis was performed on patients with analyzable angiographic images. Categorical variables were presented as counts and percentages, and compared by means of the Fisher's exact test. Continuous variables were presented as mean ± standard deviation and were compared using the Mann–Whitney *U*-test. A value of $P < 0.05$ was considered statistically significant. Statistical analysis was performed with SPSS 12.0.1 for Windows (SPSS, Chicago IL).

RESULTS

Patient Demographic and Lesion Characteristics

A total of 30 patients were enrolled in the ABSORB trial between March 2006 and July 2006. Three of the 30 were excluded. In one patient, the stent did not pass through the target lesion. This was a clinical device failure. In another patient, angiographic images were not analyzable because there was no matched view for acute stent recoil assessment. In the other patient, catheter calibration was impossible. Hence, the BVS group included 27 patients with 27 lesions. As the 3.0 × 18 mm BVS was launched at the end of enrollment, this stent size was deployed in only one patient, with the other 26 patients receiving the 3.0 × 12 mm BVS.

In the SPIRIT FIRST and II trials, 89 patients (27 from the SPIRIT FIRST trial and 62 from the SPIRIT II trial) were treated with a single EES of 3.0 × 18 mm for a single de novo lesion. From this population, in order to match the number of the patients in the BVS group with that in the control group, we selected the first 27 consecutive patients with successful EES implantation and analyzable angiography for acute stent recoil assessment. This control group consisted of 19 patients with 19 lesions from the SPIRIT FIRST trial and 8 patients with 8 lesions from the SPIRIT II trial.

Clinical, angiographic, and procedural data are shown in Table I. Both groups shared similar patient demographics. Although neither American College of Cardiology/American Heart Association lesion complexity class type A nor C lesion was observed, lesion complexity was greater in the EES group than in the BVS group, but this difference did not reach the statistical significance ($P = 0.10$). Calcified lesions, identified by core laboratory and classified as moderate or severe grade, tended to be more frequent in the BVS group (30% vs. 15%, $P = 0.33$). Stent-to-artery ratio (defined as mean diameter of the last balloon at the highest pressure divided by baseline reference vessel diameter) and maximum balloon pressure during the entire procedure showed no significant differences between the groups.

QCA and Acute Stent Recoil Results

QCA assessments of pre- and post-PCI are shown in Table II. Baseline results were similar between the groups, except for the lesion length, which was rela-

TABLE I. Clinical, Angiographic, and Procedural Characteristics

	BVS ($N = 27$)	EES ($N = 27$)	P value
Age (years)	62.5 ± 9.2	63.7 ± 9.6	0.53
Male, *n* (%)	15 (56)	16 (59)	1.0
Diabetes, *n* (%)	1 (4)	2 (7)	1.0
Hypertension, *n* (%)	19 (70)	20 (74)	1.0
Hypercholesterolemia, *n* (%)	21 (78)	17 (63)	0.37
Current smoking, *n* (%)	6 (22)	5 (19)	1.0
Prior myocardial infarction, *n* (%)	2 (7)	7 (26)	0.14
Lesion location, *n* (%)			
Right coronary artery	6 (22)	9 (33)	0.54
Left anterior descending	13 (48)	12 (44)	1.0
Left circumflex artery	8 (30)	6 (22)	0.76
ACC/AHA lesion type, *n* (%)			
Type A	0 (0)	0 (0)	NA
Type B1	17 (63)	10 (37)	0.10
Type B2	10 (37)	17 (63)	0.10
Type C	0 (0)	0 (0)	NA
Lesion calcification, *n* (%)	4 (15)	8 (30)	0.33
Stent/artery ratio	1.06 ± 0.11	1.11 ± 0.17	0.19
Maximum pressure (atm)	16.3 ± 3.07	15.4 ± 3.00	0.24

ACC/AHA, American College of Cardiology/American Heart Association; NA, not applicable.

TABLE II. Angiographic Results at Pre- and Post-PCI

	BVS ($N = 27$)	EES ($N = 27$)	P value
Pre-PCI			
Lesion length (mm)	9.1 ± 3.9	10.5 ± 2.7	0.06
Reference vessel diameter (mm)	2.72 ± 0.48	2.67 ± 0.42	0.90
Minimum lumen diameter (mm)	1.08 ± 0.24	0.99 ± 0.27	0.37
Diameter stenosis (%)			
Post-PCI	59.3 ± 11.5	62.7 ± 9.6	0.36
Minimum lumen diameter (mm)	2.30 ± 0.32	2.43 ± 0.30	0.03
Diameter stenosis (%)	17.0 ± 7.4	11.3 ± 4.2	0.0003

tively longer in the EES group than in the BVS group (10.5 ± 2.7 mm vs. 9.1 ± 3.9 mm, $P = 0.06$). After PCI, as compared to the EES group, the BVS group had significantly smaller MLD (2.30 ± 0.32 mm vs. 2.43 ± 0.30 mm, $P = 0.03$) and significantly larger diameter stenosis (17.0% ± 7.4% vs. 11.3% ± 4.2%, $P = 0.0003$).

Table III presents the results of QCA parameters related to acute stent recoil assessment. Acute absolute and percent recoil of the BVS were higher than those of the EES, but the differences did not reach statistical significance (0.20 ± 0.21 mm [95% CI: 0.11–0.28] vs. 0.13 ± 0.21 mm [95% CI: 0.05–0.22], $P = 0.32$; 6.9% ± 7.0% [95 % CI: 4.1–9.6] vs. 4.3% ± 7.1% [95% CI: 1.5–7.1], $P = 0.25$, respectively).

TABLE III. Angiographic Parameters Related With Acute Stent Recoil Assessment

	BVS ($N = 27$)	EES ($N = 27$)	P value
Mean diameter of balloon at the highest pressure (mm)	2.86 ± 0.34	2.92 ± 0.32	0.55
Mean diameter of stent immediately after balloon inflation (mm)	2.67 ± 0.40	2.78 ± 0.30	0.18
Acute absolute recoil (mm)	0.20 ± 0.21	0.13 ± 0.21	0.32
Acute percent recoil (%)	6.9 ± 7.0	4.3 ± 7.1	0.25

TABLE IV. Relationship of Angiographic and Procedural Variables With Acute Percent Stent Recoil

	BVS			EES		
	Number	% Recoil	P value	Number	% Recoil	P value
Reference vessel diameter						
≥3.0 mm	8	3.1 ± 6.4	0.14	6	0.7 ± 9.1	0.18
<3.0 mm	19	8.4 ± 6.7		21	5.3 ± 6.3	
Stent/artery ratio (stent oversizing)						
≥1.1	10	8.4 ± 5.7	0.25	14	8.2 ± 4.1	0.003
<1.1	17	5.9 ± 7.6		13	0.3 ± 7.3	
Maximum balloon pressure						
>16 atm	7	5.9 ± 5.4	0.62	8	2.7 ± 6.1	0.24
≤16 atm	20	7.2 ± 7.5		19	4.9 ± 7.5	
Lesion calcification						
Yes	4	11.8 ± 4.3	0.06	8	5.8 ± 6.2	0.52
No	23	6.0 ± 7.0		19	3.6 ± 7.5	

Relationship of Angiographic and Procedural Variables With Acute Percent Stent Recoil

Table IV shows the relationship of angiographic and procedural variables with the acute percent stent recoil. For both groups, smaller reference vessel diameter (<3.0 mm) and lower maximum balloon pressure (≤16 atm) led to higher percent recoil, although no statistical relationship was found. Stent oversizing (stent-to-artery ratio ≥ 1.1) induced significantly higher percent recoil of the EES (8.2% ± 4.1% vs. 0.3% ± 7.3%, $P = 0.0003$), while this factor was not correlated with acute stent recoil of the BVS (8.4% ± 5.7% vs. 5.9 ± 7.6%, $P = 0.25$). There was a trend toward more recoil of the BVS in calcified lesions than in noncalcified lesions (11.8% ± 4.3% vs. 6.0% ± 7.0%, $P = 0.06$). However, this trend was equivocal in the EES group (5.8% ± 7.2% in calcified lesions and 3.6% ± 7.5% in noncalcified lesions, $P = 0.52$).

DISCUSSION

The principal finding from the present study is that in selected patients, in vivo acute stent recoil of the BVS is slightly larger, but not significantly different from that of the EES.

The main function of metallic stents is to scaffold the vessel wall and prevent early elastic recoil and acute vessel closure. The need for this property is limited to the period ranging from the time of PCI to several months, thereafter, when the stented segment is fully endothelialized and vascular damage has healed. Beyond this period, the scaffolding properties of the stent are probably unnecessary. Their permanent presence induces chronic inflammation between the metal and surrounding tissue [2], which causes in-stent neointimal hyperplasia and thrombogenesis. Further, metallic stents prevent the lumen expansion associated with late favorable remodeling sometimes seen following balloon angioplasty [14,15], impair the vessel geometry, and interfere with surgical reintervention [16] and with recently developed coronary imaging modalities such as multislice computed tomography and magnetic resonance imaging. These imaging modalities may become the default noninvasive diagnostic tool for CAD patients in the near future [17]. To fulfill the short-term need for scaffolding vessel walls and overcome the aforementioned drawbacks of metallic stents, the concept of bioabsorbable polymer stents is attractive. From preclinical studies, the BVS is predicted to be fully metabolized to carbon dioxide and water and to be fully absorbed between 2 and 3 years after implantation. Therefore, the healed natural vessels are left behind, which may no longer require antiplatelet therapy and will no longer restrict potential surgical revascularization of the stented segment. In addition, the absence of metallic stents is amenable to noninvasive imaging modalities (Fig. 1E and F) and may be adaptive to late positive remodeling. However, as polymers are more flexible than metals, there is potential that the radial strength of bioabsorbable polymer stents may be lower than that of metallic stents. Consequently, there has been concern that more acute stent recoil might occur after bioabsorbable polymer stent deployment than after metallic stent deployment. The present study is the first report of a comparison of in vivo acute stent recoil between a bioabsorbable polymer stent and a metallic stent.

In previous human clinical trials, acute stent recoil varied between 3% and 15% following Wiktor or Palmaz-Schatz stent implantation [12,13,18–21]. The wide range of BMS recoil was related in part to differences in stent material and design and in part to the difference in definitions of recoil. Stent recoil was usually defined as the difference between the minimum balloon diameter and the MLD poststent implantation. However, usage of minimum variables, proposed by previous investigators, has the potential for assessing only a part of the stented segment, because the balloon does not expand uniformly, causing asymmetric stent expansion. To reflect the behavior of the vessel wall of the entire stented segment, we used mean variables and defined acute stent recoil as the difference between the mean diameter of the last inflated balloon and the mean luminal diameter immediately after the last balloon deflation. Our study demonstrated that the acute percent stent recoil of the BVS was 6.9%, which is slightly more than the EES recoil (4.3%), but in line with previously reported in vivo conventional metallic stent recoil [12,13,18–21]. It is noteworthy that, if we adopted the definition using minimum variables to this study, the acute percent stent recoil of the BVS and EES would be calculated as 8.0% ± 10.1% and 6.8% ± 9.7%, respectively ($P = 0.72$), which are also in accordance with previously reported in vivo BMS recoil [20,21]. Taking these results into consideration, the BVS has no less detectable acute stent recoil than the metallic stents in diseased human coronary arteries.

The idea of bioabsorbable stents is not new. Since metallic stents were introduced, several types of polymeric stents have been tested in experimental studies. The Igaki-Tamai stent was the first polymeric stent examined in diseased human coronary arteries [22]. This was a self-expanding coil stent, composed of a high-molecular-weight PLLA monofilament (321 kDa) with a zigzag helical design. Its acute stent recoil assessed by QCA was 22%, which is numerically higher than that of the BVS in our study. Again, this is partly because the definition of stent recoil was different. Acute recoil of the Igaki-Tamai stent was defined as the difference between the maximum balloon diameter and the MLD post stent implantation. If this definition was applied to our study, acute stent recoil of the BVS would be 25.5%, which is similar to the recoil after the Igaki-Tamai stent implantation. Although the stent body of the BVS resembles the Igaki-Tamai stent, one difference between both stents is that the BVS is coated with the antiproliferative drug, everolimus. Considering the fact that angiographic and clinical follow-up results of patients treated with the Igaki-Tamai stent were comparable to those of BMS, the BVS may lead to better short- and intermediate-term angiographic and clinical outcomes than does BMS, because of suppression of the intimal hyperplastic response by everolimus.

Since stent recoil is the resultant of the balance between the elastic recoil and radial strength of the stent, along with the elastic properties of the arterial wall, it can be affected by several lesion or procedural characteristics, such as reference vessel diameter, stent oversizing, maximum balloon pressure, and the presence of lesion calcification. In the EES group, only stent oversizing correlated with acute stent recoil in accordance with previous reports [13]. Conversely, no

relationship was found in the BVS group between these lesion or procedural characteristics, although there was a trend toward higher recoil in patients with calcified lesions. This discrepancy between the BVS and EES may be based on the difference in their composition and design. However, these findings were derived from only a small number of patients, and the technical and clinical relevance remains unclear. Larger studies are needed to assess the association between lesion and procedure-related variables and acute stent recoil of the BVS.

Limitations

Limitations of the present study include the small number of patients. The lack of statistically significant differences in acute percent stent recoil between the BVS and EES may be due to the small sample size. To detect the difference of acute percent stent recoil between both stents at a 5% significance level with 80% power in a prospective analysis according to the result of this study, 117 patients would be needed in each group. Our study population consisted of patients enrolled in three different trials, in which inclusion/exclusion criteria varied. This may have introduced some bias, although we carefully selected the control patients to adjust baseline and lesion characteristics. Target lesions treated with the BVS were relatively simple, and acute stent recoil of the BVS may increase in more complex lesions. In addition, detailed lesion characteristics, such as plaque composition and lesion eccentricity, were unknown, because we evaluated acute stent recoil only by QCA, and not by intravascular ultrasound or optical coherence tomography. Lastly, the present study evaluated BVS recoil immediately after its implantation. Further investigations are warranted to determine the recoil properties of the BVS beyond this period.

CONCLUSIONS

In vivo acute stent recoil of the BVS is slightly larger but insignificantly different from that of the EES. This implies that the BVS may have good radial strength similar to the metallic stent. The BVS may result in angiographic and clinical outcomes comparable to the drug-eluting metallic stents at short- and intermediate-term follow-up.

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