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# Serial Angiography and Intravascular Ultrasound: Results of the SISC Registry (Stents In Small Coronaries)

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**Objectives** The aim of this study was to evaluate the novel CardioMind Sparrow (CMS) stent (CardioMind, Inc., Sunnyvale, California) against the Multi-Link Pixel (MLP) stent (Guidant Corp., Santa Clara, California) for small vessel percutaneous coronary intervention (PCI).

**Background** The CMS consists of a guidewire-based, self-expandable, ultra-thin nitinol stent with smaller profile and improved flexibility and deliverability. The performance of this novel device against a standard balloon-expandable stent for small vessel PCI has not been determined.

**Methods** Twenty-one patients were treated with the CMS and compared with 30 patients treated with MLP. Only single de novo lesions $<$14 mm in length, in native vessels of 2.0 to 2.5 mm were included. The primary goal was the comparison of quantitative coronary angiography lumen loss and intravascular ultrasound intimal hyperplasia (IH) formation between groups at 6 months.

**Results** Clinical characteristics were similar between groups. The CMS cohort had smaller vessels (2.20 $\pm$ 0.20 mm vs. 2.43 $\pm$ 0.16 mm, $p < 0.0001$) and shorter lesions (10.86 $\pm$ 3.19 mm vs. 13.12 $\pm$ 2.79 mm, $p = 0.0091$). Six-month late loss was significantly lower among CMS cohort (0.73 $\pm$ 0.57 mm vs. 1.11 $\pm$ 0.72 mm, $p = 0.038$). By intravascular ultrasound, 6-month IH volume was similar between groups (1.45 $\pm$ 0.46 $mm^3$/mm vs. 1.65 $\pm$ 1.02 $mm^3$/mm, $p = 0.50$). However, CMS presented a mean 13.39% expansion of its volumes, resulting in a significantly lower percentage of IH volumetric obstruction (31.94 $\pm$ 8.19% vs. 39.90 $\pm$ 4.72%, $p = 0.0005$).

**Conclusions** Despite producing similar amounts of IH volume, the self-expanding CMS stent presented chronic expansion of its volumes, better accommodating the neoformed tissue and resulting in significantly lower late loss and percent of IH volumetric obstruction in comparison with the MLP stent. (J Am Coll Cardiol Intv 2010;3:191–202) © 2010 by the American College of Cardiology Foundation

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Percutaneous coronary interventions (PCI) in small coronary arteries represent up to 35% of all catheter-based procedures in the daily practice (1). Despite their high frequency, there is a well-defined inverse correlation between acute and long-term success and reference vessel diameter, meaning that patients with lesions in small coronary arteries are at higher risk of procedure failure and adverse events during their follow-up (2–5). In particular, the rates of stent restenosis in the small vessel scenario are markedly higher when compared with stent restenosis rates in large vessels (1,3,5–8).

Currently, a majority of market-approved stents deployed in small coronary arteries have a higher metal-to-artery ratio, which might contribute to increasing local inflammatory response, thus also increasing the risk of subacute thrombosis and restenosis (1).

Pre-clinical data have shown that self-expanding (SE) stents could better match the vessel size with lesser deep-vessel injury, carrying the potential for inducing less in-stent neointimal tissue formation (9,10). Clinical studies have shown that SE and balloon-expanding (BE) stents have similar angiographic and clinical outcomes in the treatment of native coronary artery lesions (11–13), with a trend toward lower incidence of edge tear in the SE group (13). Nevertheless, it is still not clear whether these advantages might translate into clinical benefit when approaching human small vessels.

We sought to compare a BE stent with a novel ultra-low-profile, on-a-wire SE stent, both dedicated to the treatment of small coronary arteries.

**Abbreviations and Acronyms**

**BE** = balloon-expanding
**IH** = intimal hyperplasia
**IVUS** = intravascular ultrasound
**MACE** = major adverse cardiac events
**MI** = myocardial infarction
**MLD** = minimal lumen diameter
**PCI** = percutaneous coronary intervention
**QCA** = quantitative coronary angiography
**RVD** = reference vessel diameter
**SE** = self-expanding

## Methods

**Study design.** The SISC (Stents In Small Coronaries) Registry is a nonrandomized study that aims to evaluate, by means of serial angiography and intravascular ultrasound (IVUS), the efficacy of the novel CardioMind Sparrow Stent Delivery System (CardioMind, Inc., Sunnyvale, California) in the treatment of small coronary artery disease in comparison with a market-approved BE stent (Multi-Link Pixel, Guidant Corp., Santa Clara, California).

**Patient selection.** Patients were eligible for coronary intervention if they had symptoms of stable angina (Canadian Cardiovascular Society class I to IV), unstable angina (Braunwald class I to III, B or C), and/or clear evidence of ischemia in noninvasive assessments.

In addition, patients were required to have a single de novo >50% stenosis, in a native epicardial coronary vessel of diameter between 2.0 and 2.5 mm (by online quantitative coronary angiography [QCA]). Lesion length should not exceed 14 mm, and pre intervention coronary Thrombolysis In Myocardial Infarction flow grade should be ≥2.

Patients treated in the setting of acute myocardial infarction (MI), those unable to take the dual antiplatelet therapy and/or with serum creatinine >2.0 mg/dl and lesions located at ostium and/or bifurcations were excluded from this registry.

To obtain a comparable population, the control group (treated with the Pixel stent) consisted of a historical cohort of patients treated under the same inclusion and exclusion criteria.

The study protocol was approved by the Institution's Research Ethics Committee, and written informed consent was obtained from all patients.

**Study objectives and end point definitions.** The primary objective of the SISC registry was to compare the efficacy of the novel CardioMind Sparrow stent in small coronaries as compared with the market-approved, thin-strut, Multi-Link Pixel stent, also designed for the treatment of coronaries of small diameter. The primary efficacy end points were determined by the luminal late loss and percent of in-stent volume obstruction measured by serial angiography (QCA) and IVUS, respectively, at 6-month follow-up.

We sought, secondarily, to investigate the mechanical properties of the 2 different devices and delivery systems as well as the respective influences on vascular remodeling and compare vessel injury due to the stent edges.

Although this study is not powered to evaluate clinical outcomes, we also present the major adverse cardiac events (MACE) up to 1 year, such as cardiac death, MI, and target lesion revascularization. Unless otherwise documented, all deaths were considered of cardiac origin. Non–Q-wave MI was defined by a rise in creatine kinase greater than twice the upper reference limit of normal with an elevated myocardial band isoform. Association with appearance of pathological Q waves (>0.04 s) in 2 or more contiguous leads configured a Q-wave MI. Target lesion revascularization was defined as any revascularization procedure (either PCI or coronary artery bypass graft) of the target lesion in the presence of angiographic restenosis and signs or symptoms of ischemia. Angiographic binary restenosis was defined as a diameter stenosis of at least 50% at follow-up angiography.

Stent thrombosis was classified according to the Academic Research Consortium definition (14).

**Device characteristics. THE MULTI-LINK PIXEL CORONARY STENT SYSTEM.** The Multi-Link Pixel stent is a balloon-expandable 316L stainless-steel bare-metal stent specifically designed for the treatment of small coronary arteries. It is a thin strut stent (99.1-$\mu$m/0.0039-inch) with a 5-crest cor-

rugated ring that offers a circumferential coverage with optimal vessel scaffolding, low recoil for precise expansion, and a low metal-to-artery ratio. It comes pre-mounted on a balloon that has a technology called short transitional edge protection, which minimizes the amount of vessel dilated outside of the stented area and potentially provides a uniform stent expansion. The balloon has 2 radio-opaque markers, located inside the balloon on the catheter shaft, which fluoroscopically mark the working length of the balloon, and between which the stent is placed.

**THE CARDIOMIND SPARROW STENT DELIVERY SYSTEM.** The CardioMind Sparrow stent delivery system comprises 2 main components: the stent, and the delivery system. The Sparrow stent is an SE, nitinol, non–drug-eluting stent with ultra-thin struts (61.0-$\mu$m/0.0024-inch) that is super-elastic at corporeal temperatures. It has a closed cell design with 3.5 (12- and 13-mm stent length) or 4.0 (18- and 19-mm stent length) diamond-shaped cells along the extension of the stent and 4.0 diamond-shaped cells or crowns distributed circumferentially. Due to its ultra-thin struts, the radial strength of the Sparrow stent is approximately 50% to 60% that of the cobalt-chromium stents available on the market, thus potentially enabling a more atraumatic tissue contact, as observed in the long-term porcine animal studies (out to 180 days—data on company files). By contrast, it provides a very low metal-to-artery ratio. The percent surface coverage of the stent to the vessel wall is approximately 8% to 12%.

The delivery system uses a retractable sleeve mechanism to mechanically constrain the stent to a small diameter. The delivery system has a 2- to 3-cm flexible, radio-opaque guidewire tip at the distal end to enable positioning within the vessel. The distal end of the stent is seated at the proximal end of the guidewire tip, whereas a second radio-opaque marker indicates the proximal end of the stent. Both radio-opaque markers highlight the pre-deployed position of the stent. The Sparrow stent is deployed through a proprietary mechanism within the delivery system, which enables the release of the stent in a precise manner (15). Contrary to standard stent systems, the CardioMind Sparrow delivery system is 0.014-inch (355.6-$\mu$m) in diameter and can be introduced through the internal lumen of any standard angioplasty balloon catheter. Figure 1 presents an illustration of the study devices.

Selection of the unconstrained diameter of the Sparrow stent is based on the processing capabilities of each stent tubing, aiming to cover the maximum range of vessel diameters. Therefore, the 3.5-mm unconstrained diameter of the Sparrow stent can stent vessels of 2.3 to 2.75 mm in diameter, whereas its 3.0-mm unconstrained diameter can stent vessels 2.0 to 2.25 mm in diameter. The optimal oversizing range expected for the Sparrow stent is 30% to 50%. This sizing range was based on results from chronic porcine studies out to 90 days with single and overlapping stents. The stents were sized at 30% and at 50% to see whether there were any differences in inflammatory or intimal hyperplasia (IH) response for either single or overlapping stents (data on company files). No differences were seen, with negligible inflammatory response and very low intimal thickness in a healthy pig model. Vessel-sizing

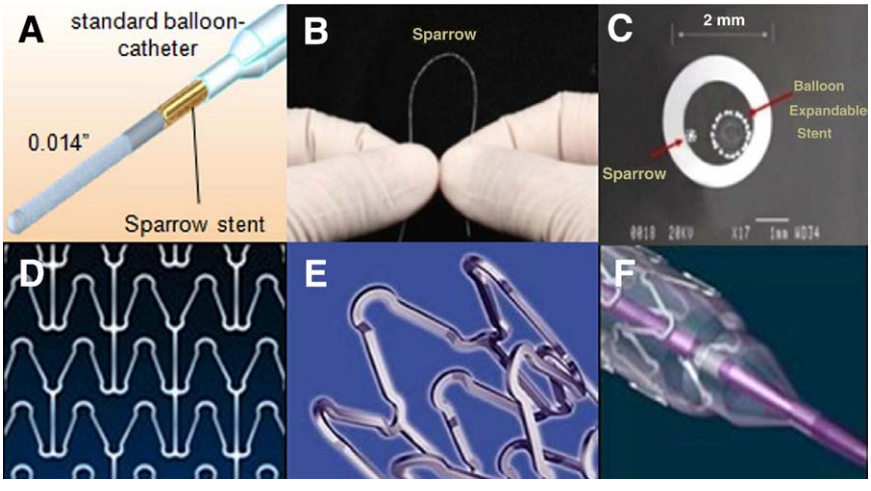


**Figure 1. Illustration of the 2 Investigated Devices**

**A, B, and C** present the main features of the Sparrow stent, and **D, E, and F** present the main features of the Multi-Link Pixel stent. **(A)** The Sparrow stent mounted on the 0.014-inch guidewire-based delivery system. Note that the balloon-catheter for pre-dilation runs over the entire system; **(B)** the marked flexibility of the CardioMind Sparrow stent delivery system; **(C)** comparison of the smaller profile of the guidewire-based Sparrow stent with a standard balloon-expandable stent inside of a 6-F guiding catheter; **(D and E)** the expanded, 5-crest, corrugated ring configuration of the Multi-Link Pixel stent; **(F)** the Multi-Link Pixel stent pre-mounted in the balloon with the short transitional edge protection technology.

below 20% might result in the stent not being secure against the vessel wall and more sensitive to dislodgement from catheters after initial implantation.

**Coronary stent procedure.** All patients were taking aspirin and a thienopyridine (clopidogrel or ticlopidine) before the coronary intervention. Aspirin (200 mg) was administered at least 24 h before the intervention. A loading dose of clopidogrel (300 mg) was administered at least 24 h before intervention, followed by 75 mg once daily. Ticlopidine dosage was 250 mg twice daily, started at least 48 h before intervention. Patients were instructed to take aspirin indefinitely. Dual antiplatelet therapy was recommended for a minimum of 3-month period for the patients who received the Sparrow stent and 1 month for those who were treated with the Pixel stent. Heparin was given as an intravenous weight-adjusted (100 IU/kg) bolus during the procedure, with additional boluses to maintain an activated clotting time >250 s. Baseline angiography was taken in at least 2 orthogonal projections after an intracoronary injection of 100 to 200 $\mu$g of nitroglycerin. The use of glycoprotein IIb/IIIa inhibitors was left at the operator's discretion.

Pre-dilation was required and performed with balloon catheters undersized at least 0.5 mm to the reference vessel diameter (RVD) in addition to being shorter than the chosen stent. After pre-dilation, the SE Sparrow stent was implanted as previously described, whereas the BE Pixel stent was implanted by the standard techniques. Use of a single stent/lesion was recommended. Additional stents could be deployed as a bailout in case of complications. When more than 1 stent was deployed, 2- to 3-mm overlapping was mandatory.

In the presence of inadequate expansion (>30% residual stenosis), the stent could be post-dilated with a balloon shorter than the implanted stent.

**Follow-up.** Serial electrocardiograms were performed before and immediately after the intervention and repeated 16 to 24 h after procedure. Creatine-kinase and creatine-kinase–myocardial band levels were recorded before intervention and repeated 6 to 8 h and 20 to 24 h after procedure.

After discharge, patients were clinically followed up by medical appointment at 1, 6, 9, and 12 months.

Angiography and IVUS studies were scheduled to be performed at 6 months (±1 month) of the baseline procedure.

**QCA analysis.** Angiographic studies were performed at baseline, after procedure, and at follow-up, in 2 orthogonal views, after the intracoronary administration of 100 to 200 $\mu$g of nitroglycerin. The same angiographic angles performed at baseline were reproduced at the subsequent studies. Digital angiograms were analyzed offline with the use of an automated edge-detection system (QCA-CMS, Medis Medical Imaging Systems, Leiden, the Netherlands).

Lesion morphology was assessed by using standard criteria, and lesion complexity was defined according to the modified American College of Cardiology/American Heart Association classification system (16). The contrast-filled guiding catheter tip was used for calibration.

The quantitative angiographic parameters included: 1) RVD; 2) minimal lumen diameter (MLD); 3) lesion length; 4) percent diameter stenosis, calculated as: $100 \times (1 - [\text{MLD}/\text{RVD}])$; 5) acute gain (difference between the baseline MLD and the in-stent MLD after stent implantation); 6) net gain (difference between the baseline MLD and the in-stent MLD at follow-up); 7) late luminal loss (difference between MLD at the end of the procedure and MLD at follow-up); and 8) loss index (late luminal loss/acute gain). Quantitative analysis was performed in the "in-stent" area (including only the stented segment) and in the "in-segment" zone, including the stented area as well as the 5 mm both proximally and distally to the stent. In-stent and in-segment restenosis were defined as ≥50% diameter stenosis at follow-up located within the stent and the target lesion, respectively.

**IVUS analysis.** The IVUS studies were performed immediately after procedure and at follow-up, after an intracoronary administration of 100 to 200 $\mu$g of nitroglycerin.

All IVUS studies were performed with a motorized automatic transducer pullback system (0.5 mm/s) and commercially available scanners (CVIS and Galaxy 2, Boston Scientific Corporation, Natick, Massachusetts) consisting of a rotating 40-MHz transducer catheter with a 2.6-F imaging sheath. The IVUS analyses were made with a commercially available computerized planimetry program (EchoPlaque 3.0, INDEC Systems, Inc., Mountain View, California).

Quantitative parameters of lumen, stent, and vessel (external elastic membrane) cross-sectional areas were determined. The IH area was calculated as the stent area minus the lumen area at the follow-up. Lumen, stent, and vessel volumes were calculated with the Simpson's rule. The IH volume was calculated by the difference between stent and lumen volumes at follow-up. The indexed volumes were calculated as: volume/stent length measured by IVUS. Percent of IH volume obstruction was determined by the IH volume at follow-up divided by the follow-up stent volume and multiplied by 100. Peri-stent volume was defined as the difference between the vessel and stent volumes.

Chronic stent expansion was defined as the stent volume at follow-up divided by the stent volume after procedure and multiplied by 100.

Incomplete stent apposition was defined as ≥1 stent strut clearly separated from the vessel wall with evidence of blood speckles behind the struts in a segment not overlapping a side branch (17) and was classified as: 1) persistent; 2) acquired; and 3) resolved (18).

**Statistical analysis.** Statistical analysis was performed with SPSS version 13.0 for Windows (SPSS, Chicago, Illinois). Categorical data are presented as counts and percentages,

and continuous data are presented as mean value ± SD. After testing the normality of the data with the Kolmogorov-Smirnov test, Fisher exact test was used for comparison of categorical variables. Continuous variables were compared by Student *t* test (paired and unpaired according to the compared data). Kaplan-Meier estimates were used to describe event-free survival for MACE, with the log-rank test employed to test group differences. A 2-tailed p value <0.05 was considered statistically significant.

## Results

Between May 2006 and January 2007, 21 patients were submitted to PCI with the Sparrow stent implantation. The control group consisted of 30 patients treated with the Pixel stent between April and December 2003.

Baseline demographic, clinical, and angiographic characteristics of both groups are shown in Table 1. The overall population mean age was 59.34 ± 9.91 years, with a predominance of men. Diabetes mellitus was highly prevalent in both groups, especially among those receiving the Sparrow stent (52.4% vs. 30%, p = 0.14).

Patients assigned to the Sparrow group had significantly smaller vessels (mean RVD 2.20 ± 0.20 mm vs. 2.43 ± 0.16 mm, p < 0.0001). Conversely, patients in the Pixel group had longer lesions (mean lesion length 10.86 ± 3.19 mm vs. 13.12 ± 2.79 mm, p = 0.0091) and more interventions to the left anterior descending coronary artery (19% vs. 46.7%, p = 0.07).

**Procedural and in-hospital outcomes.** Procedural data are presented in Table 2. Device, angiographic, and procedure successes were obtained in all patients. There were 1.14 stents/lesions used in the Sparrow group and 1.0 stent/lesion used in the Pixel group. In the beginning of the learning curve, the Sparrow stent was misplaced in 3 cases, requiring additional stent deployment (same type). Despite the differences regarding baseline RVD and lesion length, the mean stent diameter (2.43 ± 0.17 mm vs. 2.49 ± 0.05 mm, p = 0.07) and mean stent length (16.44 ± 5.12 mm vs. 17.33 ± 4.30 mm, p = 0.50) were similar between the 2 groups. Post-stenting dilation was performed more frequently in the Sparrow group when compared with the Pixel group (100% vs. 20%, p < 0.0001). Nevertheless, the maximal balloon/RVD ratio (1.2 ± 0.2 vs. 1.1 ± 0.2, p = 0.08) and final maximum inflation pressures (14.5 ± 3.5 atm vs. 14.4 ± 1.9 atm, p = 0.90) were similar between the 2 groups.

Vessels in patients treated with the BE Pixel stent showed a significantly higher post-procedure in-stent MLD (2.39 ± 0.13 mm vs. 2.08 ± 0.25 mm, p < 0.0001)

**Table 1. Baseline Demographic, Clinical, and Angiographic Characteristics**

| | Overall (n = 51) | Sparrow (n = 21) | Pixel (n = 30) | p Value |
|---|---|---|---|---|
| Age (yrs) | 59.34 ± 9.91 | 61.94 ± 10.9 | 56.75 ± 8.92 | 0.079 |
| Male | 31 (60.8) | 14 (66.6) | 17 (56.6) | 0.56 |
| Arterial hypertension | 39 (76.5) | 16 (76.2) | 23 (76.6) | >0.99 |
| Diabetes mellitus | 20 (39.2) | 11 (52.4) | 9 (30) | 0.14 |
| Hyperlipidemia | 38 (74.5) | 18 (85.7) | 19 (63.3) | 0.11 |
| Current smoker | 17 (33.3) | 8 (38.1) | 9 (30) | 0.56 |
| Prior MI | 21 (41.2) | 10 (47.6) | 11 (36.6) | 0.56 |
| Prior PCI | 17 (33.3) | 6 (28.6) | 11 (36.6) | 0.76 |
| Prior CABG | 2 (3.9) | 1 (4.7) | 1 (3.3) | >0.99 |
| Stable angina | 38 (74.5) | 15 (71.4) | 23 (76.6) | 0.75 |
| Unstable angina | 9 (17.6) | 2 (9.5) | 7 (23.3) | 0.27 |
| Normal LV function | 40 (78.4) | 15 (71.4) | 25 (83.3) | 0.32 |
| Target vessel | | | | 0.02 |
| LAD | 18 (35.3) | 4 (19.0) | 14 (46.7) | |
| LCx | 20 (39.2) | 9 (42.9) | 11 (36.7) | |
| RCA | 13 (25.5) | 8 (38.1) | 5 (16.6) | |
| Type B2/C* lesions | 23 (45.1) | 4 (24.8) | 19 (63.3) | 0.37 |
| RVD, mm | 2.33 ± 0.21 | 2.20 ± 0.20 | 2.43 ± 0.16 | <0.0001 |
| Lesion length, mm | 12.11 ± 3.18 | 10.86 ± 3.19 | 13.12 ± 2.79 | 0.0091 |
| MLD, mm | 0.68 ± 0.25 | 0.62 ± 0.27 | 0.72 ± 0.24 | 0.16 |
| Diameter stenosis, % | 70.60 ± 11.13 | 71.31 ± 13.17 | 70.13 ± 9.75 | 0.71 |

Values are mean ± SD or n (%). *American College of Cardiology/American Heart Association classification.

CABG = coronary artery bypass graft; LAD = left anterior descending artery; LCx = left circumflex; MI = myocardial infarction; MLD = minimal lumen diameter; PCI = percutaneous coronary intervention; RCA = right coronary artery; RVD = reference vessel diameter.

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**Table 2. Procedural Data**

| | Sparrow (n = 21) | Pixel (n = 30) | p Value |
|---|---|---|---|
| Mean stent diameter, mm | 2.43 ± 0.17 | 2.49 ± 0.05 | 0.07 |
| Mean stent length, mm | 16.44 ± 5.12 | 17.33 ± 4.30 | 0.50 |
| Stent length/lesion length ratio | 1.63 ± 0.44 | 1.38 ± 0.45 | 0.06 |
| After dilation | 21 (100) | 6 (20) | <0.0001 |
| Maximal inflation pressure, atm | 14.50 ± 3.50 | 14.41 ± 1.88 | 0.90 |
| Maximal balloon/reference artery diameter ratio | 1.2 ± 0.2 | 1.1 ± 0.2 | 0.08 |
| Number of stents used | 24 | 30 | N/A |
| Stents/lesion ratio | 1.14 ± 0.50 | 1.0 | N/A |
| MLD after procedure, mm | 2.08 ± 0.25 | 2.39 ± 0.13 | <0.0001 |
| Diameter stenosis after procedure, % | 15.75 ± 7.07 | 5.86 ± 2.15 | <0.0001 |
| Acute gain, mm | 1.46 ± 0.41 | 1.68 ± 0.22 | 0.016 |
| Device success | 21 (100) | 30/30 (100) | N/A |
| Angiographic success | 21 (100) | 30/30 (100) | N/A |
| Procedure success | 21 (100) | 30/30 (100) | N/A |

Values are mean ± SD, n (%), or n.
Abbreviations as in Table 1.

and acute gain (1.68 ± 0.22 mm vs. 1.46 ± 0.41 mm, p = 0.016), resulting in a lower residual diameter stenosis (5.86 ± 2.15% vs. 15.75 ± 7.07%, p < 0.0001), when compared with the SE nitinol Sparrow stent.

No MACE were noticed during the hospital stay period.

**Angiographic results at follow-up.** Angiographic follow-up was performed at 7.2 ± 1.0 months. One patient in the Sparrow group declined the invasive follow-up. As a result, the angiographic study was performed in 20 (95.2%) patients in the Sparrow group and in all patients in the Pixel group.

Table 3 shows the QCA follow-up results. In contrast to the post-procedure evaluation, the SE Sparrow stent showed a larger although not statistically significant in-stent MLD (1.35 ± 0.60 mm vs. 1.28 ± 0.74 mm, p = 0.69) and lower in-stent percent diameter stenosis (38.12 ± 26.77% vs. 46.82 ± 30.17%, p = 0.28) when compared with the BE Pixel stent. Therefore, the primary angiographic end point of late luminal loss was significantly smaller in the Sparrow group as compared with the Pixel group (0.73 ± 0.57 mm vs. 1.11 ± 0.72 mm, p = 0.038). Figure 2 shows the cumulative frequency distribution curves for MLD in both groups. Binary restenosis was found in 4 (20%) lesions in the Sparrow group compared with 10 (33.3%) in the Pixel group (p = 0.34). There were 5 occlusive restenosis in the Pixel group compared with none in the Sparrow group.

No edge dissections were detected in either group.

**Table 3. Quantitative Angiography Results at Follow-Up**

| | Sparrow (n = 20) | Pixel (n = 30) | p Value |
|---|---|---|---|
| RVD, mm | 2.17 ± 0.20 | 2.44 ± 0.16 | <0.0001 |
| In-stent MLD, mm | 1.35 ± 0.60 | 1.28 ± 0.74 | 0.72 |
| In-segment MLD, mm | 1.31 ± 0.54 | 1.26 ± 0.73 | 0.79 |
| In-stent DS, % | 38.12 ± 26.77 | 46.82 ± 30.17 | 0.29 |
| In-segment DS, % | 39.87 ± 24.51 | 76.65 ± 35.09 | 0.0001 |
| Net gain, mm | 0.73 ± 0.71 | 0.57 ± 0.72 | 0.43 |
| In-stent late loss, mm | 0.73 ± 0.57 | 1.11 ± 0.72 | 0.038 |
| In-segment late loss, mm | 0.61 ± 0.51 | 0.83 ± 0.67 | 0.21 |
| Loss index | 0.53 ± 0.43 | 0.67 ± 0.43 | 0.25 |
| In-stent binary restenosis | 4 (20) | 10 (33.3) | 0.34 |

Values are mean ± SD or n (%).
DS = diameter stenosis; other abbreviations as in Table 1.

**In-stent IVUS results.** For the 21 patients who received the Sparrow stent, post-procedure IVUS was performed in 18 patients. At the 6-month planned follow-up, IVUS volumetric analysis was performed in 15 patients, but after excluding the cases with inadequate images for analysis, serial volumetric IVUS images were available for 13 (61.9%) patients.

For the 30 patients who received the Pixel stent, post-procedure IVUS was performed in 27 patients. At the 6-month planned follow-up, serial IVUS volumetric analysis was available for 25 (83.3%) patients.

Table 4 presents the baseline (after procedure) and follow-up in-stent quantitative IVUS results. The IVUS parameters assessed after procedures were comparable between the 2 groups.

At 6-month follow-up, vessels stented with the Sparrow and the Pixel stents resulted in similar amounts of IH volume (1.45 ± 0.46 $mm^3/mm$ vs. 1.65 ± 1.02 $mm^3/mm$, respectively; p = 0.50). Consequently, both groups presented significant reductions of lumen volumes from baseline, with lesser change in the Sparrow group (from 4.02 ± 0.9 $mm^3/mm$ to 3.07 ± 0.68 $mm^3/mm$ in the Sparrow

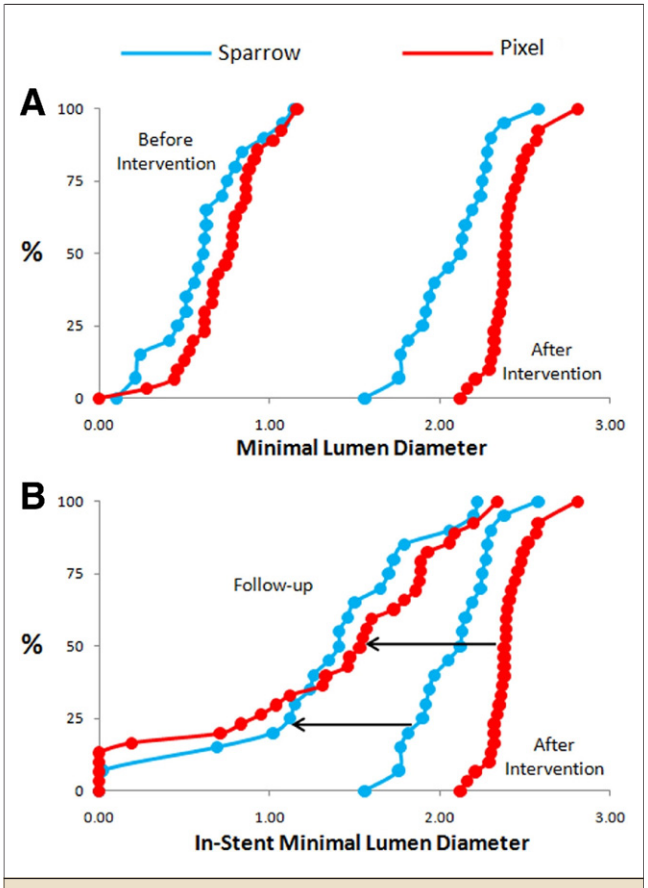


**Figure 2. In-Stent Minimal Lumen Diameter Distribution Curves**

In-stent minimal lumen diameter cumulative frequency distribution curves for the Sparrow and Pixel stents. **(A)** The cumulative frequency distribution curves before and immediately after the intervention. **(B)** The curves immediately after intervention and at 6-month follow-up angiography.

group, p = 0.005; and from 4.22 ± 1.03 $mm^3$/mm to 2.65 ± 1.34 $mm^3$/mm in the Pixel group, p < 0.0001).

Notably, vessels treated with the SE nitinol Sparrow stent presented an 13.39 ± 11.08% additional expansion of stent volumes from baseline, whereas those vessels stented with the stainless steel BE Pixel stent showed a nonsignificant (1.79 ± 16.58%) change in its volumes throughout the follow-up period (p = 0.02 for the comparison between the 2 groups) (Figs. 3 and 4). In fact, despite the similar amount of IH generated by the 2 devices, the chronic expansion of the Sparrow stent better accommodated this newly formed tissue, thus accounting for a significant reduction of the percent of IH volumetric in-stent obstruction when compared with those treated in the Pixel group (31.94 ± 8.19% vs. 39.90 ± 4.72%, p = 0.0005).

In addition, the vessel volume index did not change significantly in either group, demonstrating that the chronic expansion of the Sparrow stent occurred at the expense of occupation of the peri-stent space and not by producing positive vascular remodeling.

In the qualitative IVUS analysis, 6 (46%) cases of acute incomplete stent apposition to the vessel wall in the Sparrow group were identified. At the follow-up IVUS evaluation, 50% of the malapposition cases were resolved. There were no cases of late-acquired incomplete stent strut apposition. In the Pixel group no cases of incomplete stent apposition were identified.

**IVUS evaluation at the stent edges.** From the overall 38 patients (13 from Sparrow group, and 25 from Pixel group) with 76 edges, who had serial IVUS runs suitable for analysis, 16 (21%) edges were excluded from the edge level analysis because of 1 or more of the following reasons: inadequate image quality for analysis (7.8%); insufficient length (<5 mm) for analysis (15.7%); and presence of significant side branch in the edge segment (5.2%). As a result, analysis of the proximal edge was possible for 12 (92.3%) patients in the Sparrow group and for 18 (72%) in the Pixel group. Analysis of the distal edge was possible for 10 (76.9%) and 20 (80%) patients in the Sparrow and Pixel groups, respectively.

Table 5 presents the quantitative IVUS results for the proximal edges, and Table 6 presents the same parameters for the distal edges.

At the post-procedure evaluation, because the RVD was significantly lower in the Sparrow group, the vessel volume

**Table 4. Serial Quantitative IVUS Data for the In-Stent Segment**

| | Sparrow (n = 13) | Pixel (n = 25) | p Value* |
|---|---|---|---|
| Stent length, mm | | | |
| Post-procedure | 19.16 ± 1.84 | 17.20 ± 4.72 | 0.16 |
| Follow-up | 19.07 ± 1.12 | 17.28 ± 4.83 | 0.19 |
| p value† | 0.88 | 0.95 | |
| Vessel volume index, $mm/mm^3$ | | | |
| Post-procedure | 8.37 ± 1.69 | 9.53 ± 2.27 | 0.11 |
| Follow-up | 8.43 ± 1.69 | 9.42 ± 2.15 | |
| p value† | 0.92 | 0.86 | 0.15 |
| Stent volume index, $mm/mm^3$ | | | |
| Post-procedure | 4.02 ± 0.90 | 4.22 ± 1.03 | 0.55 |
| Follow-up | 4.52 ± 0.42 | 4.24 ± 0.98 | 0.33 |
| p value† | 0.08 | 0.94 | |
| Lumen volume index, $mm/mm^3$ | | | |
| Post-procedure | 4.02 ± 0.90 | 4.22 ± 1.03 | 0.55 |
| Follow-up | 3.07 ± 0.68 | 2.65 ± 1.34 | 0.29 |
| p value† | 0.005 | <0.0001 | |
| Persistent volume index, $mm/mm^3$ | | | |
| Post-procedure | 4.35 ± 0.94 | 5.31 ± 1.60 | 0.054 |
| Follow-up | 3.91 ± 0.94 | 5.18 ± 1.51 | 0.0091 |
| p value† | 0.24 | 0.76 | |
| IH volume index, $mm/mm^3$ | 1.45 ± 0.46 | 1.65 ± 1.02 | 0.50 |
| % IH volumetric obstruction | 31.94 ± 8.19 | 39.90 ± 4.72 | 0.0005 |

*Unpaired Student *t* test; †paired Student *t* test.
IH = intimal hyperplasia; IVUS = intravascular ultrasound.

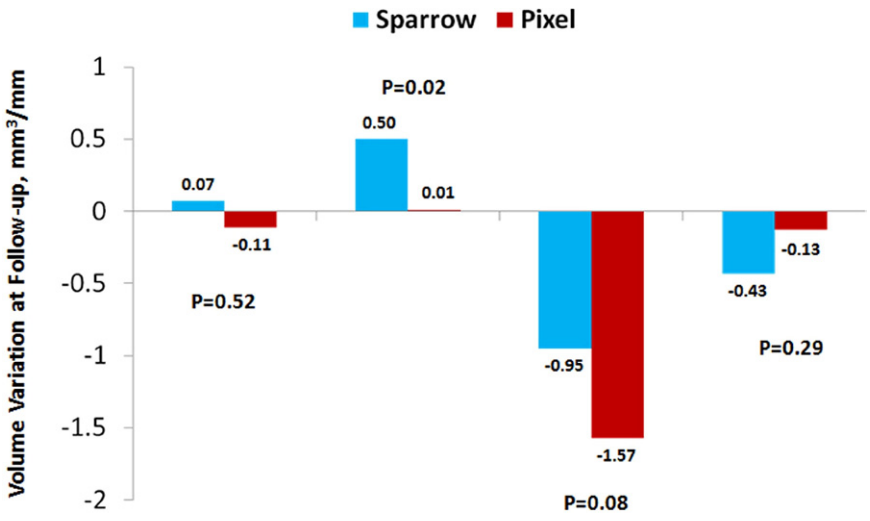


**Figure 3. In-Stent Intravascular Ultrasound Assessment**

Intravascular ultrasound quantitative evaluation of volume changes at the in-stent segment for the Sparrow and Pixel stents between post-procedure examination and 6-month follow-up.

index was significantly smaller in the distal edge (6.33 ± 2.20 $mm^3$/mm vs. 8.06 ± 2.15 $mm^3$/mm, p = 0.04), and there was a trend for a lower volume in the proximal edge (9.00 ± 1.25 $mm^3$/mm vs. 11.05 ± 3.60 $mm^3$/mm, p = 0.07), compared with the Pixel group. There were no significant differences between the 2 groups regarding the baseline indexed volumes of lumen, plaque, and plaque burden. Yet, the Sparrow group showed a trend toward a

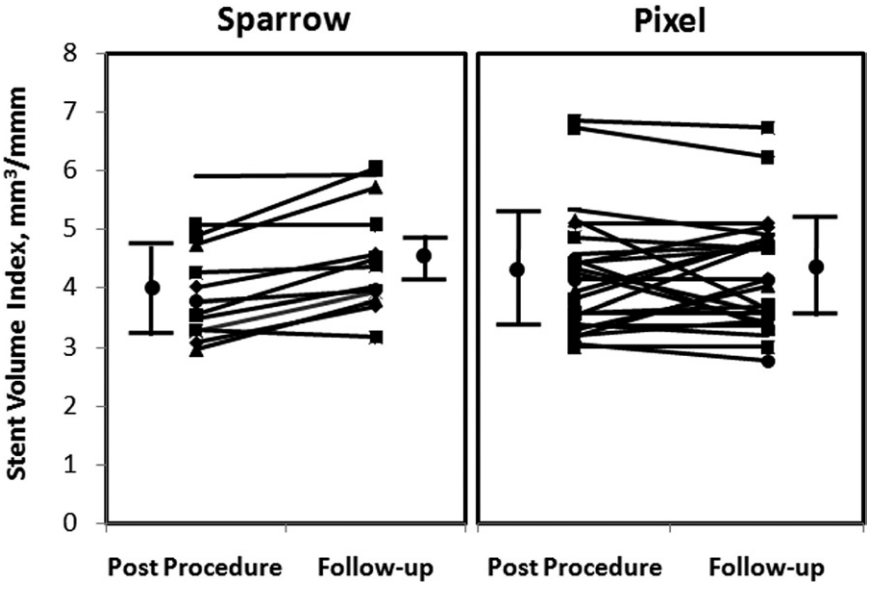


**Figure 4. Intravascular Ultrasound Stent Volume Variation**

Intravascular ultrasound evaluation of stent volume index change from post-procedure examination to 6-month follow-up, for the Sparrow and Pixel stents. Neither stent presented a significant intra-group change in its volumes over time (Sparrow stent: 4.02 ± 0.90 $mm^3$/mm to 4.22 ± 1.03 $mm^3$/mm, p = 0.55; Pixel stent: 4.52 ± 0.42 $mm^3$/mm to 4.24 ± 0.98 $mm^3$/mm, p = 0.33). However, when comparing the 2 stent systems, a significant increase of 13.39 ± 11.08% of the Sparrow stent over the 6-month follow-up period was identified, in comparison with the 1.79 ± 16.58% change in the Pixel stent (p = 0.02). **Vertical bars** illustrate mean ± SD.

**Table 5. Serial Quantitative IVUS Data for the Proximal Edge**

| | Sparrow (n = 12) | Pixel (n = 18) | p Value* |
|---|---|---|---|
| Analyzed length, mm | | | |
| Post-procedure | 4.64 ± 0.75 | 4.82 ± 0.55 | 0.45 |
| Follow-up | 4.49 ± 0.96 | 4.86 ± 0.48 | 0.18 |
| p value† | 0.67 | 0.82 | |
| Vessel volume index, mm/mm$^3$ | | | |
| Post-procedure | 9.00 ± 1.25 | 11.05 ± 3.60 | 0.07 |
| Follow-up | 8.65 ± 2.21 | 10.33 ± 3.69 | 0.16 |
| p value† | 0.63 | 0.55 | |
| Plaque volume index, mm/mm$^3$ | | | |
| Post-procedure | 4.52 ± 1.56 | 5.46 ± 2.01 | 0.18 |
| Follow-up | 4.32 ± 1.56 | 5.22 ± 2.05 | 0.20 |
| p value† | 0.75 | 0.72 | |
| Lumen volume index, mm/mm$^3$ | | | |
| Post-procedure | 4.49 ± 1.11 | 5.35 ± 2.40 | 0.25 |
| Follow-up | 4.33 ± 1.06 | 5.11 ± 2.63 | 0.33 |
| p value† | 0.72 | 0.77 | |
| Minimal lumen area, mm$^2$ | | | |
| Post-procedure | 3.51 ± 0.83 | 4.57 ± 1.81 | 0.07 |
| Follow-up | 3.30 ± 1.06 | 4.26 ± 1.56 | 0.07 |
| p value† | 0.59 | 0.58 | |
| Plaque burden, % | | | |
| Post-procedure | 49.02 ± 12.07 | 50.61 ± 12.54 | 0.60 |
| Follow-up† | 49.01 ± 9.46 | 51.37 ± 12.97 | 0.73 |
| p value | 0.99 | 0.85 | |

*Unpaired Student *t* test; †paired Student *t* test.
IVUS = intravascular ultrasound.

smaller minimal lumen area in the proximal edge (3.51 ± 0.83 mm$^2$ vs. 4.57 ± 1.81 mm$^2$, p = 0.07).

At 6-month follow-up, the minimal lumen area at the distal edge was significantly smaller in the Sparrow group (2.49 ± 0.79 mm$^2$ vs. 3.83 ± 1.31 mm$^2$, p = 0.01). However, no significant changes were observed in the vessel, plaque, and lumen indexed volumes between the 2 groups at the 6-month IVUS evaluation (Fig. 5, Table 6).

Moreover, no significant differences were detected regarding the volumes (vessel, plaque, and lumen), minimal lumen area, and plaque burden between the proximal and distal edges for vessels treated with either of the 2 stents (Table 7).

No case of residual edge dissection was observed in either cohort.

**Late clinical events.** One-year complete clinical follow-up was obtained for all patients from both cohorts, and there were no significant differences in the incidence of MACE between the groups (Fig. 6).

In the Sparrow group, 1 patient experienced a sudden death after 7 months of the index procedure. In this case, the Sparrow stent had been implanted in the mid-LAD (2.0 mm RVD), and at the 6-month invasive follow-up, the patient was completely asymptomatic and presented a 46% in-stent diameter stenosis by QCA. Nevertheless, this event was adjudicated as a cardiac death, and with the definitions devised by the Academic Research Consortium, this case was also classified as having experienced a probable stent thrombosis.

In the Pixel group, there were no cases of death or MI. Six patients developed ischemic symptoms, and 4 (13.3%) required repeat target lesion revascularization. Two patients presented with focal in-stent restenosis and were treated by conventional balloon angioplasty. The other 2 patients developed significant stenosis in other territories in addition to a diffuse pattern of restenosis and were referred to coronary artery bypass graft surgery. No cases of stent thrombosis were detected in this group.

## Discussion

The SISC registry is the first report of the clinical use of the CardioMind Sparrow stent in comparison with a standard market-approved balloon-expandable stent. The main findings of the present analysis are: 1) SE nitinol and BE 316L stainless-steel stents produced a similar amount of IH tissue up to 6 months; 2) the Sparrow stent expanded by 13% during the 6-month follow-up period, becoming able to

**Table 6. Serial Quantitative IVUS Data for the Distal Edge**

| | Sparrow (n = 10) | Pixel (n = 20) | p Value* |
|---|---|---|---|
| Analyzed length, mm | | | |
| Post-procedure | 5.00 ± 0 | 4.92 ± 0.36 | >0.99 |
| Follow-up | 4.72 ± 0.89 | 4.91 ± 0.40 | 0.42 |
| p value† | 0.99 | 0.93 | |
| Vessel volume index, mm/mm$^3$ | | | |
| Post-procedure | 6.33 ± 2.20 | 8.06 ± 2.15 | 0.04 |
| Follow-up | 6.64 ± 2.16 | 7.16 ± 2.58 | 0.58 |
| p value† | 0.75 | 0.23 | |
| Plaque volume index, mm/mm$^3$ | | | |
| Post-procedure | 2.78 ± 1.35 | 3.48 ± 1.56 | 0.23 |
| Follow-up | 3.05 ± 1.54 | 3.10 ± 1.92 | 0.94 |
| p value† | 0.68 | 0.49 | |
| Lumen volume index, mm/mm$^3$ | | | |
| Post-procedure | 3.80 ± 1.29 | 4.49 ± 1.34 | 0.19 |
| Follow-up | 3.59 ± 1.13 | 3.87 ± 1.31 | 0.57 |
| p value† | 0.70 | 0.14 | |
| Minimal lumen area, mm$^2$ | | | |
| Post-procedure | 3.11 ± 1.01 | 3.83 ± 1.31 | 0.13 |
| Follow-up | 2.49 ± 0.79 | 3.50 ± 1.07 | 0.01 |
| p value† | 0.14 | 0.39 | |
| Plaque burden, % | | | |
| Post-procedure | 43.66 ± 12.56 | 42.47 ± 12.97 | 0.81 |
| Follow-up | 44.86 ± 11.75 | 41.20 ± 13.71 | 0.47 |
| p value† | 0.82 | 0.76 | |

*Unpaired Student *t* test; †paired Student *t* test.
IVUS = intravascular ultrasound.

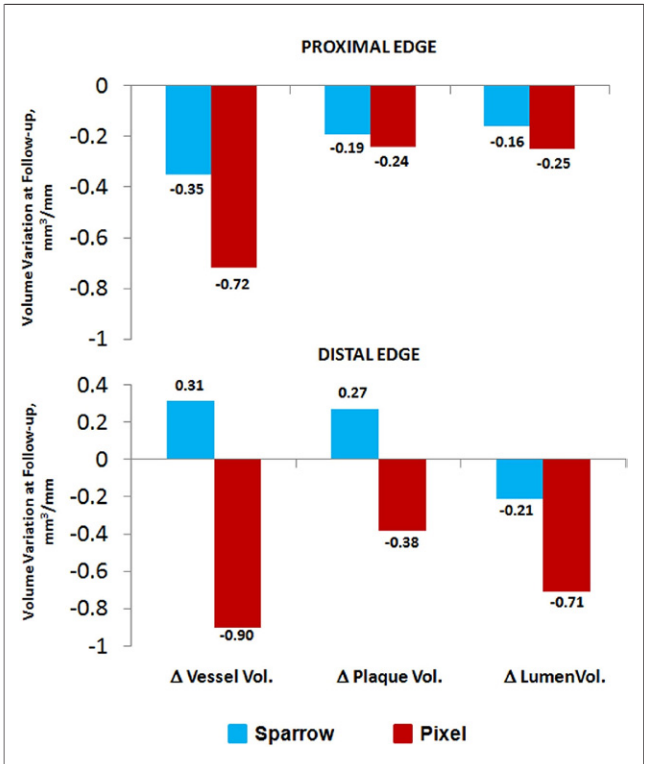


**Figure 5. IVUS Assessment of Stent Edges**

Intravascular ultrasound (IVUS) quantitative evaluation of volume (Vol.) changes at the proximal and distal edges for the Sparrow and Pixel stents between post-procedure examination and 6-month follow-up (p = NS for all comparisons).

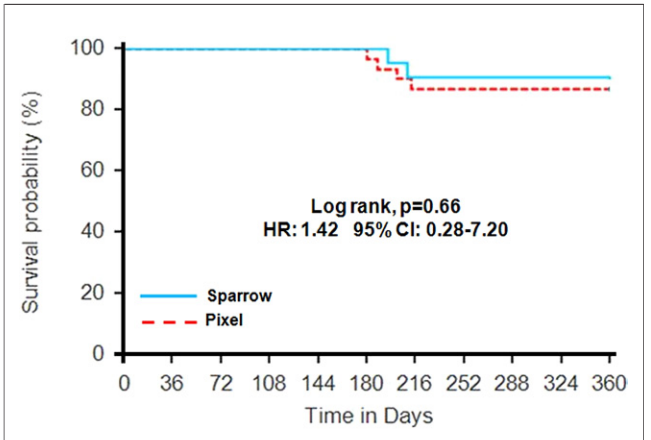


**Figure 6. 12-Month Survival Free of MACE**

Kaplan-Meier estimate of survival free from major adverse cardiac events (MACE; defined as cardiac death, myocardial infarction, and target-lesion revascularization) up to 12 months of follow-up for the patients treated with the Sparrow stent and Pixel stent. There were no significant differences between the 2 cohorts (p = 0.66 by the log-rank test). CI = confidence interval; HR = hazard ratio.

better accommodate the newly formed tissue and resulting in a significantly lower percentage of in-stent volumetric obstruction; and 3) this phenomenon occurred essentially by compression of the plaque located between the stent struts and vessel wall and not by a vascular positive remodeling.

The advent of drug-eluting stents has markedly reduced overall restenosis rates and clinical outcomes as compared with bare-metal stents in the treatment of coronary artery disease (19–22). Moreover, randomized trials and subgroup analysis have demonstrated that this benefit also extends to the small vessel subset (23–28).

However, despite the advances in drug-eluting stent technology, with the development of low-profile, thin-strut stents, the clinical benefits of drug-eluting stents might not be fully achieved in distal or calcified lesions or those with excessive tortuosity or vessels previously implanted with stents, due to the limited deliverability and accessibility of the current balloon-expandable stents in these types of anatomies. This might be one of the reasons for a low procedural success rate observed in small-vessel PCI (29,30).

To address this issue, the CardioMind Sparrow stent system has the lowest profile ever developed for a coronary stent system. As previously mentioned, the design incorporates an SE nitinol stent, with ultra-thin strut thickness, which is mounted in a shapeable, steerable guidewire-type delivery platform, maintaining its 0.014-inch profile along the entire stent system (15). Nitinol is a nickel-titanium alloy that possesses thermoelastic properties, which allows self-expansion of the

**Table 7. Changes in Intravascular Parameters of the Proximal and Distal Edges Between Baseline and Follow-Up**

| | Sparrow | | | Pixel | | |
|---|---|---|---|---|---|---|
| | Proximal Edge | Distal Edge | p Value* | Proximal Edge | Distal Edge | p Value* |
| Δ VVI, mm³/mm | −0.35 ± 0.86 | 0.31 ± 1.30 | 0.17 | −0.72 ± 2.80 | −0.90 ± 2.14 | 0.82 |
| Δ PVI, mm³/mm | −0.19 ± 0.76 | 0.27 ± 0.35 | 0.09 | −0.24 ± 1.70 | −0.38 ± 1.33 | 0.77 |
| Δ LVI, mm³/mm | −0.16 ± 0.74 | −0.21 ± 0.88 | 0.88 | −0.25 ± 1.80 | −0.71 ± 1.49 | 0.39 |
| Δ MLA, mm² | −0.21 ± 0.77 | −0.63 ± 1.30 | 0.35 | −0.32 ± 1.38 | 0.05 ± 1.86 | 0.49 |
| Δ plaque burden, % | −0.01 ± 7.12 | 1.21 ± 10.80 | 0.75 | 0.76 ± 11.76 | −1.27 ± 8.03 | 0.53 |

*Unpaired Student *t* test.
LVI = lumen volume index; MLA = minimal lumen area; PVI = plaque volume index; VVI = vessel volume index.

stent up to a predefined point, theoretically, decreasing the chronic injury and inflammation seen after the implantation of first-generation SE stents (31).

The IVUS studies have demonstrated that the degree of final luminal diameter in vessels <2.75 mm in diameter is predictive of the likelihood of repeat revascularization (24). The pattern and timing of injury after placement of an SE stent is different from that of the BE stents. Whereas BE stents achieve their final diameter immediately after the procedure, SE stents demonstrate ongoing expansion after their implantation, reaching their final diameter at a later time after the procedure (31). This characteristic might allow a gentler approach in the deployment of the self-expandable stent, to enable the accomplishment of optimal luminal volumes with less balloon barotrauma and consequently less IH formation.

Historical data have suggested the more frequent occurrence of edge dissection after the implant of balloon-expanding stents (11), which has not been confirmed in the present evaluation. The deployment of the Pixel stents with intermediate pressures performed after dilation with short noncompliant balloons, whenever necessary, might partially help to demonstrate the equivalent performance between the cohorts.

Finally, these encouraging preliminary clinical results, with the use of the Sparrow stent, have led to the development of a drug-eluting version for this platform. Currently ongoing, the CARE (CARdiomind lEsions) II trial compares, in a multicenter prospective randomized study, the SE nitinol CardioMind Sparrow stent with its drug-eluted equivalent (with Sirolimus in a fully biodegradable polymer) and with a market-approved bare-metal BE stent (Microdriver, Medtronic, Minneapolis, Minnesota).

**Study limitations.** There are 3 main limitations of this study—the first being the nonrandomized nature of the study. To minimize selection bias, patients in the historical control group were treated under the same inclusion/exclusion criteria. However, some baseline angiographic differences could be noted; the different duration of dual antiplatelet therapy is another issue that deserves comment. Because the technique of stent implantation differs between groups (self- vs. balloon-expandable) and once the SE stent presents a chronic expansion of its volumes over time—achieving its final diameter much later than the balloon-expanding stents–it is reasonable to accept a longer period of dual antiplatelet treatment in the Sparrow group, as a rational to prevent thrombosis. Finally, the small sample size was underpowered to identify differences in clinical outcomes between the cohorts.

## Conclusions

The SE nitinol CardioMind Sparrow guidewire-based stent system produced an equivalent amount of IH as the thin-strut balloon-expanding Multi-Link Pixel stent. In addition, vessels treated with this novel device experienced an ongoing expansion of its stent volumes, which seems to better accommodate the neointimal tissue and thus generates a significant lower in-stent volumetric obstruction, which in turn might translate into improved clinical outcomes.

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**Key Words:** angioplasty ■ balloon-expanding ■ intravascular ultrasound ■ QCA ■ self-expanding ■ small vessels ■ stents.