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REVIEW

# New stent design for use in small coronary arteries during percutaneous coronary intervention



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**Abstract:** Patients with diabetes mellitus, of female gender, increased age, and/or with peripheral vascular disease often develop coronary stenoses in small caliber vessels. This review describes treatment of these lesions with the paclitaxel-eluting 2.25 mm TAXUS® Liberté® Atom™ stent. Given the same stent composition, polymer, antirestenotic drug (paclitaxel), and release kinetics as the first-generation 2.25 mm TAXUS® Express® Atom™ stent, the second-generation TAXUS Liberté Atom stent incorporates improved stent design characteristics, including thinner struts (0.0038 versus 0.0052 inches), intended to increase conformability and deliverability. In a porcine noninjured coronary artery model, TAXUS Liberté Atom stent implantation in small vessels demonstrated complete strut tissue coverage compared with the bare metal stent control, suggesting a similar degree of tissue healing between the groups at 30, 90, and 180 days. The prospective, single-armed TAXUS ATLAS Small Vessel trial demonstrated improved instent late loss (0.28 ± 0.45 versus 0.84 ± 0.57 mm, $P < 0.001$), instent binary restenosis (13.0% versus 38.1%, $P < 0.001$), and target lesion revascularization (5.8% versus 17.6%, $P < 0.001$) at nine months with the TAXUS Liberté Atom stent as compared with the bare metal Express stent control, with similar safety measures between the two groups. The TAXUS Liberté Atom also significantly reduced nine-month angiographic rates of both instent late loss (0.28 ± 0.45 versus 0.44 ± 0.61 mm, $P = 0.03$) and instent binary restenosis (13.0% versus 25.9%, $P = 0.02$) when compared with the 2.25 mm TAXUS Express Atom control. The observed reduction in target lesion revascularization with the TAXUS Liberté Atom compared with the TAXUS Express Atom at nine months (5.8% versus 13.7%, $P = 0.02$) was sustained through three years (10.0% versus 22.1%, $P = 0.008$) with similar, stable safety outcomes between the groups. In conclusion, these data confirm the safety and favorable performance of the TAXUS Liberté Atom stent in the treatment of small coronary vessels.

**Keywords:** small vessel, paclitaxel, stent

## Introduction

Treatment of small vessels, historically defined as <3.0 mm in diameter, constitutes an estimated 30%–50% of all percutaneous coronary interventions.[1,2] As interventional practice has developed, vessels <2.5 to 2.75 mm by visual estimate are currently considered to be small vessels.[3] Female gender, diabetes mellitus, increased age, and peripheral vascular disease are often associated with small vessel coronary atherosclerotic lesions.[4–6] The increasing prevalence of diabetes, along with prolonged life expectancy, will likely increase the number of small coronary vessels requiring treatment. Although the use of bare metal stents versus plain balloon angioplasty has reduced restenosis and major adverse cardiac events among patients undergoing percutaneous coronary intervention in coronary vessels ≥3.0 mm,[7,8] several studies

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comparing bare metal stenting versus balloon angioplasty in small vessels have demonstrated conflicting and inconclusive clinical and angiographic results.[9–11] The introduction of drug-eluting stents in the treatment of small coronary vessels has shown favorable and improved outcomes in this high-risk subgroup of patients.[12–16] This review examines the use of the paclitaxel-eluting TAXUS® Liberté® Atom™ 2.25 mm stent in the treatment of very small coronary vessels (2.25–2.5 mm vessel diameter).

## Challenges of small vessel stent implantation

Performing interventional procedures on small vessels presents a number of technical challenges. Delivering a stent to a given lesion in a small vessel may be hampered by more difficult visualization, distal and branch vessel locations, vessel tortuosity, and greater lesion complexity, including calcification. Distal lesions are also more frequently diffuse, requiring longer, more flexible stents to cover the diseased segment.

Endothelial injury, as well as deeper arterial wall trauma, usually occurs following stent implantation. Injury stimulates excessive smooth muscle cell proliferation, with consequent migration into the intima, leading to neointimal hyperplasia, the primary mechanism of late lumen loss and instent restenosis.[17,18]

A comparison of clinical restenosis between bare metal and drug-eluting stents demonstrated a difference in the restenosis patterns, with a more focal restenosis in the drug-eluting stents compared with bare metal stents, and a higher incidence of bifurcation lesions in the drug-eluting cohort. Neointimal tissue within instent restenotic lesions was observed to be similar between drug-eluting stents and bare metal stents, and comprised mainly proteoglycan-rich smooth muscle cells and fibrolipidic areas rich in collagen and reticular fibers. Although no difference in smooth muscle cell proliferation rate was observed between drug-eluting stent and bare metal stent samples, the smooth muscle cell phenotype was characterized as contractile or intermediate in the drug-eluting stent samples, and synthetic phenotype in the bare metal stent samples, suggesting different mechanisms of restenosis.[19]

Although drug-eluting stents reduce neointimal hyperplasia and resulting late lumen loss compared with bare metal stents, lesions located in small vessels are more prone to develop hemodynamically significant restenosis compared with those in larger vessels.[20,21] A possible explanation is that small vessels have a limited ability to accommodate lumen renarrowing after percutaneous coronary intervention, an outcome attenuated following implantation of a thinner strut stent.[22] This may explain why no bare metal stent has received US Food and Administration (FDA) approval for vessels ≤2.5 mm in diameter.[23] The combined challenges of deliverability, lesion complexity, and increased restenosis in smaller vessels highlight the need for dedicated stent systems to treat this ever-increasing subset of patients.

## TAXUS Liberté Atom stent system components

### Drug

Paclitaxel, derived from the Pacific yew tree (*Taxus brevifolia*), delays restenosis by binding and stabilizing the assembly of microtubules, thereby arresting cellular replication in the $G_0/G_1$ and $G_1/M$ phases.[24] In contrast, the -olimus (rapamycin) drugs diminish microtubule activity by inhibiting mTOR, a key intermediary in the PI-3-kinase pathway.[25] In human arterial smooth muscle cells, paclitaxel binds β-tubulin dimers and inhibits their depolymerization resulting in stable microtubules. This nonfunctional assembly of microtubules disrupts a variety of cellular processes, resulting in the inhibition of smooth muscle cell migration and proliferation and, ultimately, neointimal hyperplasia and restenosis.[26–28] Importantly, paclitaxel does not cause smooth muscle cell apoptosis.[24] Paclitaxel is insoluble in water, which minimizes loss to the blood during stent implantation and facilitates tissue uptake when in contact with the arterial wall. The highly lipophilic nature of paclitaxel enhances cellular uptake, resulting in effective inhibition of neointimal formation.[29]

### Polymer

The TAXUS Liberté Atom coronary stent uses a soft, hydrophobic, elastomeric triblock copolymer known as Translute™ (styrene-b-isobutylene-b-styrene).[30] This polymer provides homogeneous coverage of paclitaxel along all stent surfaces, retention and protection of paclitaxel during routine handling of the stent, controlled local target delivery of paclitaxel, and long-term vascular compatibility. The TAXUS polymer formulation provides an early burst release of paclitaxel in the first 48 hours to blunt the initial response to implant injury, followed by a lower level of paclitaxel release for approximately 10 days to maintain this inhibited inflammatory response and yet allow for vascular healing.

### Stent

The TAXUS Liberté Atom 2.25 mm stent evolved from the FDA-approved first-generation TAXUS Express Atom

2.25 mm stent (Boston Scientific Corporation, Natick, MA) with the aim of providing enhanced lesion access and more homogeneous drug distribution in small vessels. Both stents consist of a 316L stainless steel stent coated with the Translute polymer containing paclitaxel in a dose density of 1 μg/mm$^2$. The Liberté stent incorporates improved stent design characteristics intended to increase conformability and deliverability into more complex lesions including, multiangled thin struts (0.0038 versus 0.0052 inches) and the elimination of long straight joining connectors (Figure 1). Thinner struts have been associated with a lower late luminal loss and less neointimal volume obstruction after stenting, possibly a result of less stent-induced arterial injury and inflammation.[31,32] The TAXUS Liberté Atom stent system features a low tip profile (0.017 inches) designed to cross tighter lesions, as well as a low stent crossing profile (0.041 inches), and a 13% more trackable stent delivery system as compared with the TAXUS Express$^2$ Atom stent system (data on file, Boston Scientific Corporation). The continuous cell design of the TAXUS Liberté Atom stent provides better vessel coverage and more uniform drug delivery along the length of the stent compared with the TAXUS Express Atom stent (Figure 2). The TAXUS Liberté Atom stent was designed to provide dedicated sizing for small vessels (2.25–2.50 mm) and is crimped on a balloon delivery catheter of a corresponding diameter.

## Preclinical testing

Extensive safety testing was conducted using a porcine coronary artery model.[33] Sixty small vessel stents (30 TAXUS Liberté Atom [paclitaxel-eluting stent] and 30 bare metal Liberté stents [bare metal]) were implanted in all three coronary arteries of 30 female domestic crossbred swine. Each animal

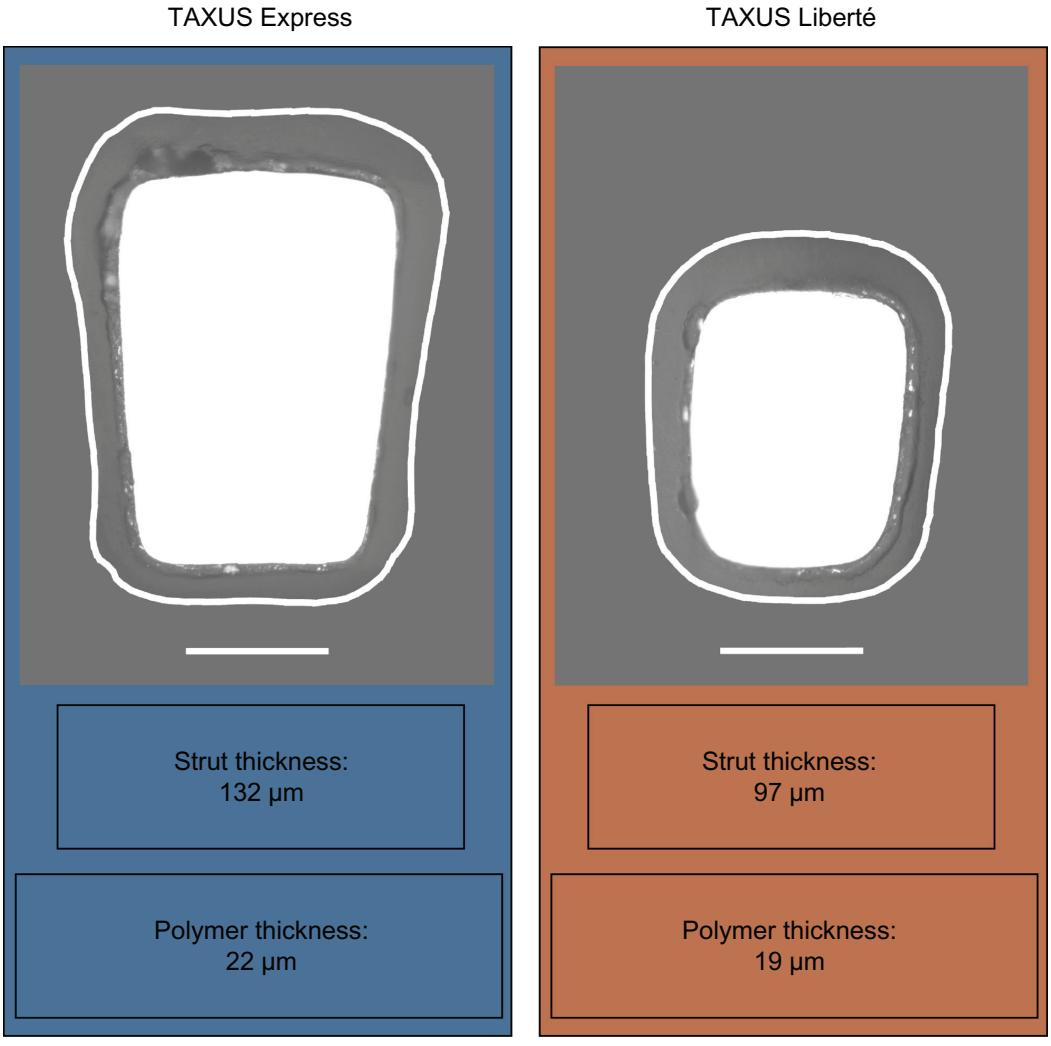


**Figure 1** Study device strut and polymer thickness. Cross-sectional scanning electron micrograph images of the TAXUS Liberté Atom and TAXUS Express Atom stents with polymer edges outlined.
**Notes:** 500× magnification, bar = 50 μm.

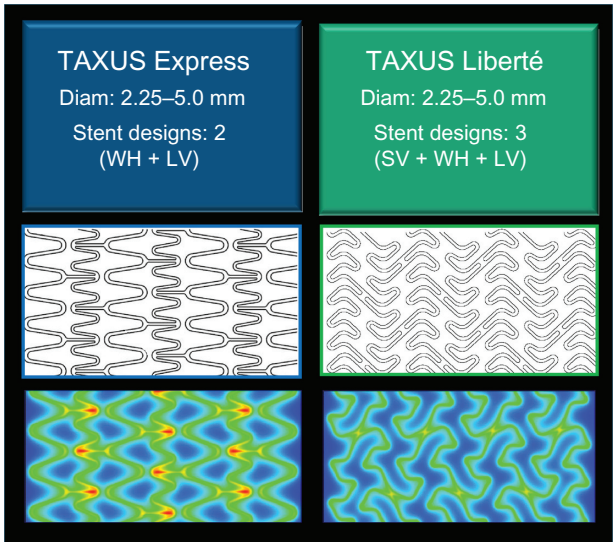


**Figure 2** TAXUS paclitaxel-eluting stent designs. Improved stent-to-artery ratio and more homogeneous drug delivery with the TAXUS Liberté stent compared with the TAXUS Express stent.
**Abbreviations:** SV, small vessel; WH, workhorse; LV, large vessel.

received one test stent (paclitaxel-eluting stent, 2.0 × 12 mm or 2.5 × 20 mm) and one control stent (bare metal stent, 2.25 × 16 mm or 2.5 × 16 mm) in separate vessels. As shown in Figure 3, TAXUS Liberté Atom demonstrated greater than 90% endothelial cell strut coverage, as assessed by scanning electron microscopy and no visible evidence of luminal thrombi at 30, 90, and 180 days. Vascular compatibility using histologic analysis demonstrated complete strut tissue coverage, complete endothelialization, a small amount of fibrin deposition, and no adverse positive or negative remodeling in both groups at 30 days, and persisting out to 90 and 180 days (Figure 4). Since delayed healing has been associated with persistent fibrin deposition and reduced or delayed endothelialization in humans,[34] the vascular response supports the favorable safety profile of the TAXUS Liberté Atom stent compared with the bare metal stent control in a noninjured swine model.

## Clinical outcomes

### Clinical trials with TAXUS stents in small vessels

The definition for small vessels varies in range from <3.0 mm (historic definition) to anywhere from <2.5 to 2.75 mm as assessed by visual estimate.[3] Since angiographic outcomes are affected by stent size and small vessel diameter,[35,36] this review focuses on either the TAXUS Liberté Atom stent size (2.25 mm) or within its indicated reference vessel diameter (≤2.5 mm). Small vessel subgroup analyses from three multicenter, randomized TAXUS trials, as well as a

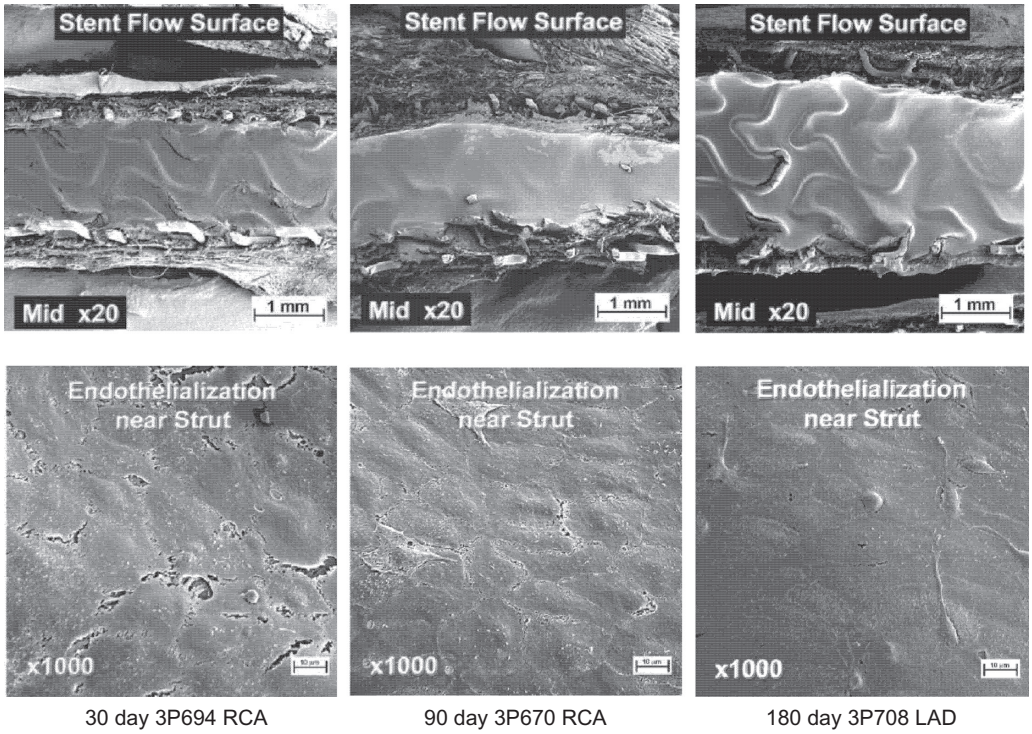


**Figure 3** Endothelialization of the TAXUS Liberté Atom stent in a noninjured porcine model. Representative scanning electron microscopy of the TAXUS. Liberte Atom stent platform in midstent segments at 30, 90, and 180 days demonstrating strut coverage by tissue with cells of endothelial morphology comprising the flow surface.

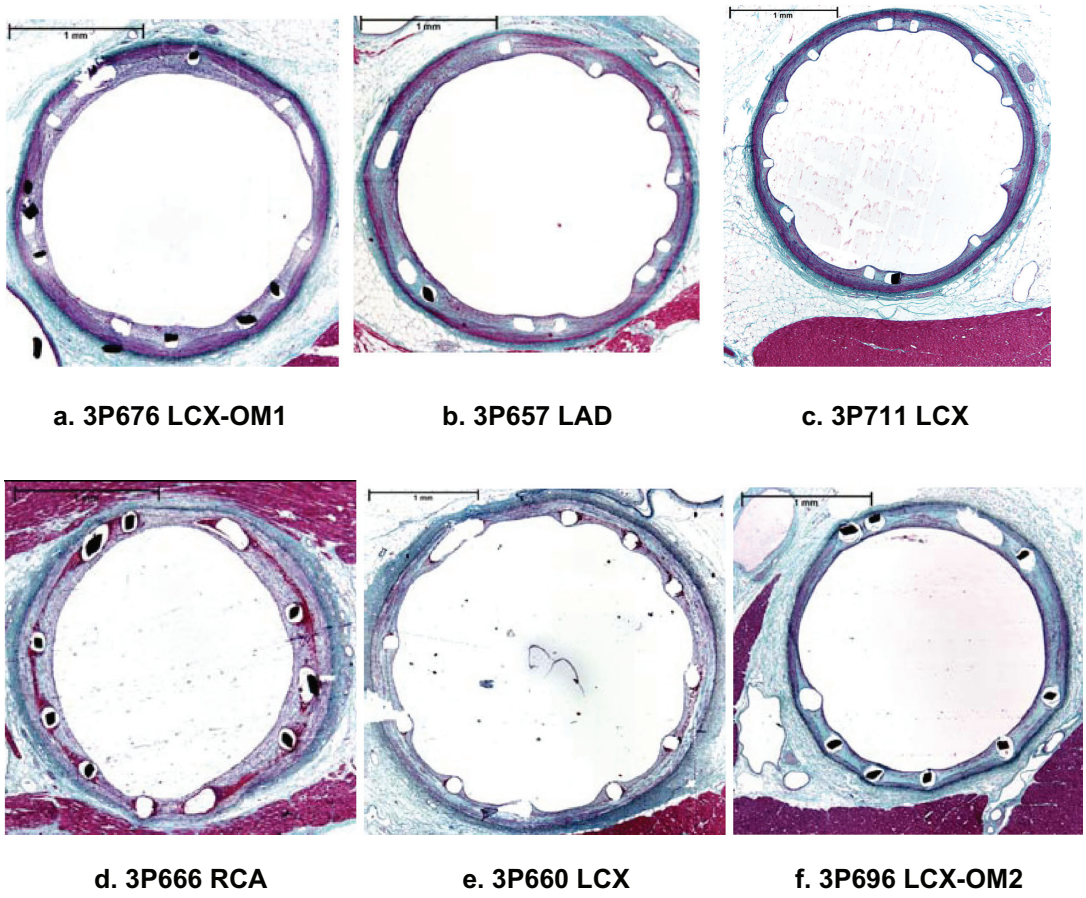


**Figure 4** Vascular compatibility using histologic analysis in a noninjured porcine model. Representative hematoxylin and eosin staining (40 × total magnification) of bare Liberté (**a–c**) and TAXUS Liberté Atom (**d–f**) mid-stent in cross section at 30 days (**a, d**), 90 days (**b, e**), and 180 days (**c, f**) postimplantation.


dedicated, prospective TAXUS Small Vessel trial are briefly described below.

## TAXUS IV trial

The TAXUS IV study evaluated the safety and effectiveness of the TAXUS Express slow-release paclitaxel eluting stent system for treatment of de novo coronary artery lesions compared with an identical Express bare metal stent control. In a small vessel subgroup of patients with a reference vessel diameter ≤2.5 mm (n = 176), the TAXUS Express-treated patients had lower nine-month insegment restenosis (10.2% versus 38.5, $P < 0.001$) and nine-month target lesion revascularization (3.4% versus 15.4, $P < 0.001$) rates than those treated with bare metal stents.[37,38] The reduction in target lesion revascularization rate following treatment of small vessels (<2.5 mm) was maintained at three years, being 8.2% in the paclitaxel-eluting stent group versus 26.9% in the bare metal stent group ($P < 0.001$).[39]

## TAXUS V trial

The TAXUS V de novo study evaluated the use of the TAXUS Express[2] slow-release paclitaxel-eluting stent system versus an Express bare metal stent control in a more complex patient population consisting of de novo lesions, reference vessel diameter 2.25–4.0 mm and a lesion length of 10 mm–46 mm. In the subgroup of patients (n = 385) with small vessels (reference vessel diameter ≤2.5 mm), lower revascularization rates were observed with paclitaxel-eluting stents when compared with bare metal stents. At two years, the target lesion revascularization rate in patients with treated small vessels was lower in paclitaxel-eluting stent-treated patients (16.6%, n = 195) compared with those receiving a bare metal stent (29.8%, $P = 0.002$, n = 190).[40] This benefit was maintained through five years (20.6% versus 33.6%, $P = 0.004$).[41]

A separate subset analysis of TAXUS V de novo patients receiving a 2.25 mm TAXUS Express stent (TAXUS Express Atom, n = 108) versus a bare metal stent (n = 95) was also

performed. The nine-month angiographic results revealed improved instent late loss (0.49 ± 0.61 versus 0.90 ± 0.63 mm, $P < 0.001$) and instent binary restenosis with paclitaxel-eluting stents (24.7% versus 44.7%, $P = 0.007$) than with bare metal stents (Table 1). The corresponding target lesion revascularization rate at nine months was lower in the paclitaxel-eluting stent group (10.4%) than in the bare metal stent group (21.5%, $P = 0.03$), with comparable rates of death, myocardial infarction, and stent thrombosis between the two groups.[21] These differences persisted through 12 months in patients treated with the 2.25 mm TAXUS Express stent.[42] At three years, the target lesion revascularization rate was still numerically lower in patients receiving the 2.25 mm TAXUS Express stent (19.6%) than in those with a bare metal stent (27.1%, $P = 0.13$), but the difference was no longer statistically significant.[43]

## TAXUS VI trial

The TAXUS VI trial was a randomized, double-blind, controlled study assessing the safety and performance of the 1 μg/mm$^2$ moderate-release formulation TAXUS Express paclitaxel-eluting stent in patients with high-risk (longer length) de novo coronary artery lesions. The TAXUS moderate-release investigational device used in this trial releases 33 μg of paclitaxel per 3.0 × 24 mm stent over 30 days (data from a preclinical animal model), approximately three times the dose released from the commercially available TAXUS slow-release stents. In the subgroup of patients (n = 124) with small vessels (reference vessel diameter <2.5 mm), the target lesion revascularization rate at nine months was significantly lower in patients receiving a paclitaxel-eluting stent (5.0%) versus a bare metal stent (29.7%, $P < 0.001$).[44] This benefit in target lesion revascularization rate was maintained at two years with the use of paclitaxel-eluting stents (8.3%) versus bare metal stents (29.5%, $P = 0.005$),[45] and continued through five years (14.0% versus 31.0%, $P = 0.02$).[46]

**Table 1** Safety and efficacy in patients receiving a 2.25 mm TAXUS Express Atom stent in the TAXUS V *de novo* study

| Parameter | TAXUS V | | |
|---|---|---|---|
| | Patients receiving a 2.25 mm stent | | |
| | TAXUS Express atom (n = 108) | BMS Express (n = 95) | *P*-value |
| **Angiographic follow-up[21]** | **9 Months** | | |
| In-stent late loss, mm | 0.49 ± 0.61 | 0.90 ± 0.63 | <0.001 |
| In-stent binary restenosis | 24.7% | 44.7% | 0.007 |
| **Clinical follow-up[21]** | **9 Months** | | |
| TLR | 10.4% | 21.5% | 0.03 |
| TVR | 16.0% | 24.7% | 0.16 |
| MACE* | 18.9% | 26.9% | 0.23 |
| Cardiac death | 1.9% | 1.1% | >0.99 |
| ST# | 1.0% | 1.1% | >0.99 |
| **Follow-up[42]** | **12 Months** | | |
| TLR | 14.6% | 24.9% | 0.047 |
| TVR | 22.6% | 30.4% | 0.26 |
| MACE* | 26.4% | 32.6% | 0.35 |
| Cardiac death | 2.8% | 1.2% | 0.63 |
| ST# | 1.0% | 1.1% | >0.99 |
| **Follow-up[43]** | **36 Months** | | |
| TLR | 19.6 | 27.1 | 0.13 |

**Notes:** *Includes cardiac death, myocardial infarction, and target vessel revascularization. #Per protocol definition.

**Abbreviations:** BMS, bare metal stent; TLR, target lesion revascularization; TVR, target vessel revascularization; MACE, major adverse cardiac event; ST, stent thrombosis.

## TAXUS ATLAS Small Vessel trial

TAXUS ATLAS (A multi-center, single-arm study of the TAXUS Liberté™-SR stent for the treatment of patients with de novo coronary artery lesions) Small Vessel was the first prospective TAXUS trial dedicated to investigation of TAXUS stent use in small vessels. The preclinical data described earlier is further supported by the results of the TAXUS ATLAS Small Vessel trial. The TAXUS ATLAS Small Vessel trial evaluated the safety and effectiveness of the 2.25 mm TAXUS Liberté (TAXUS Liberté Atom) stent in the treatment of de novo coronary artery lesions in patients with small vessels, compared with historic controls drawn from the TAXUS V randomized clinical trial. A total of 261 patients, with a reference vessel diameter 2.2–2.5 mm (visual estimate), from 23 investigational sites were enrolled to receive a 2.25 mm TAXUS Liberté stent. The trial had two prespecified control groups, ie, a bare metal stent control (n = 155) comprising TAXUS V patients treated with either a 2.25 mm or 2.5 mm bare metal Express stent or a TAXUS Express control (n = 75) comprised of TAXUS V patients treated with a 2.25 mm TAXUS Express (TAXUS Express Atom) stent. Patients received dual antiplatelet therapy (clopidogrel or ticlopidine and aspirin) for a minimum of six months (aspirin for a minimum of nine months), and were scheduled for quantitative coronary angiography at nine months. The study met its primary nine-month superiority endpoint compared with bare metal stents and the nine-month noninferiority endpoint compared with TAXUS Express for insegment % diameter stenosis.

The nine-month angiographic results revealed improved instent late loss (0.28 ± 0.45 versus 0.84 ± 0.57 mm, $P < 0.001$) and instent binary restenosis (13.0% versus 38.1%, $P < 0.001$) with the paclitaxel-eluting stent than with the bare metal stent control.[47,48] The corresponding target

lesion revascularization rate at nine months was lower in the paclitaxel-eluting stent group (5.8%) than in the bare metal stent group (17.6%, $P < 0.001$), with comparable rates of death, myocardial infarction, and stent thrombosis between the two groups.[47]

When compared with the 2.25 mm TAXUS Express stent, the 2.25 mm TAXUS Liberté stent significantly reduced the nine-month angiographic rates of both instent late loss ($0.44 \pm 0.61$ versus $0.28 \pm 0.45$ mm, $P = 0.03$) and instent binary restenosis (25.9% versus 13.0%, $P = 0.02$) as well as the nine-month target lesion revascularization rate (13.7% versus 5.8%, $P = 0.02$) in the small vessel population[47] (Table 2). The reduction in target lesion revascularization rate with the TAXUS Liberté compared with the TAXUS Express control was maintained at 12 months (6.1% versus 16.9%, $P = 0.004$), at two years (8.2% versus 20.3%, $P = 0.005$), and at three years (10.0% versus 22.1%, $P = 0.008$), with similar safety outcomes throughout the small vessel population.[49–51] An independent multivariate analysis revealed that treatment with the TAXUS Liberté significantly reduced the risk of target lesion revascularization versus the TAXUS Express through three years (hazard ratio 0.34; 95% confidence interval 0.17–0.66, $P = 0.001$).[51]

**Table 2** Principle safety and effectiveness data of the 2.25 mm TAXUS Liberté Atom stent in small vessels in the TAXUS ATLAS Small Vessel trial

| Parameter | TAXUS ATLAS Small Vessel | | |
|---|---|---|---|
| | Case-matched (2.2–2.5 mm RVD) patients | | |
| | TAXUS Liberté Atom (n = 261) | TAXUS Express Atom (n = 75) | *P*-value |
| **Angiographic follow-up[47]** | **9 Months** | | |
| In-stent late loss, mm | $0.28 \pm 0.45$ | $0.44 \pm 0.61$ | 0.03 |
| In-stent binary restenosis | 13.0% | 25.9% | 0.02 |
| **Clinical follow-up[47]** | **9 Months** | | |
| TLR | 5.8% | 13.7% | 0.02 |
| TVR | 10.1% | 17.8% | 0.07 |
| MACE* | 12.8% | 20.5% | 0.10 |
| Cardiac death | 0.8% | 2.7% | 0.46 |
| ST# | 0.4% | 1.4% | 0.39 |
| **Follow-up[50]** | **24 Months§** | | |
| TLR | 8.2% | 20.3% | 0.005 |
| TVR | 12.8% | 26.1% | 0.007 |
| MACE | 16.5% | 30.4% | 0.01 |
| Cardiac death | 2.1% | 4.3% | 0.38 |
| ST# | 0.8% | 1.5% | 0.52 |
| **Follow-up[51]** | **36 Months§** | | |
| TLR | 10.0% | 22.1% | 0.008 |
| TVR | 15.2% | 27.9% | 0.02 |
| MACE* | 19.5% | 32.4% | 0.03 |
| Cardiac death | 2.6% | 4.4% | 0.43 |
| ST# | 1.4% | 1.5% | >0.99 |

**Notes:** *Includes cardiac death, myocardial infarction, and target vessel revascularization. #Academic Research Consortium definite/probable definition. §Consists of patients who received a study stent at baseline.

**Abbreviations:** TLR, target lesion revascularization; TVR, target vessel revascularization; MACE, major adverse cardiac event; ST, stent thrombosis.

## Summary

The three TAXUS trial subgroup analyses and the dedicated TAXUS ATLAS Small Vessel trial demonstrate an overall consistent and sustained lowering of late loss and angiographic and clinical restenosis with the TAXUS stents compared with bare metal stent controls in small vessels.

## Registry data with TAXUS stents in small vessels

TAXUS ARRIVE (Peri-Approval Registry: A Multi-Center Safety Surveillance Program) included two consecutively enrolling, multicenter safety surveillance registries in the US (ARRIVE 1 and ARRIVE 2). The program captured usage patterns and two-year outcomes with the TAXUS Express stent in 7492 patients treated during routine practice, including 4794 patients who would have been excluded from pivotal randomized controlled trials.[52,53] In the combined registry cohort of patients with reference vessel diameter <2.5 mm (n = 251), target lesion revascularization was 7.5% in the first year and 1.3% in the second year. In the ARRIVE 1 small vessel subgroup (reference vessel diameter ≤2.5 mm, n = 743) target lesion revascularization was 6.6% after 12 months and 2.7% in the second year.

TAXUS OLYMPIA was a multicenter, prospective, global registry capturing safety and clinical outcomes in patients receiving the TAXUS Liberté stent in routine clinical practice. From a preliminary population of 22,345 patients, the 12-month target lesion revascularization rate was 2.8% and composite cardiac event (cardiac death, myocardial infarction, and target vessel revascularization) rate was 4.8% in treated patients (n = 2460) with small vessels (<2.5 mm).[54]

The TAXUS ARRIVE and TAXUS OLYMPIA registries have reported low safety event rates and acceptable clinical outcomes when treating small vessels with either TAXUS Express or TAXUS Liberté stents. These outcomes observed in routine interventional practice further support the findings from the TAXUS randomized clinical trials.

## Sirolimus-eluting 2.25 mm stent in small vessels

In addition to the TAXUS Express Atom and the TAXUS Liberté Atom stents, a third 2.25 mm drug-eluting stent that has

received FDA approval is the CYPHER® sirolimus-eluting BX-velocity stent system (Cordis Corporation, Bridgewater, NJ). The CYPHER Mini (2.25 mm) is mounted on a rapid exchange stent delivery system with a crimped profile of 0.044 inches. The pivotal trial for approval of the 2.25 mm CYPHER drug-eluting stent was SIRIUS 2.25, the primary endpoint of which was six-month binary restenosis, revealed to be at a rate of 16.9%, with a target lesion revascularization rate at six months of 4.0% compared with 15.0% in historic bare metal stent controls.[55] A comparison of target lesion revascularization rates between the CYPHER 2.25 mm stent in SIRIUS 2.25 and the TAXUS Liberté 2.25 mm stent from the TAXUS ATLAS Small Vessel trial reveal numerically similar outcomes at 12 months (7.0% versus 6.1%) and at two years (9.0% versus 8.2%).[49,50,56] Numerically similar target lesion revascularization rates were also observed with the TAXUS Liberté Atom and the CYPHER stent in trials with vessels ≤2.75 mm in diameter.[57,58] Target lesion revascularization with TAXUS Liberté 2.25 mm at 12 months (6.1%)[48] and at 24 months (8.2%)[49] compared favorably with the sirolimus-eluting stent at 12 months (6.6%)[56] and at 24 months (7.9%).[57] Definitive conclusions cannot be drawn from an indirect comparison between sirolimus- and paclitaxel-eluting stents because appropriately powered clinical trials directly comparing the TAXUS Liberté Atom stent and the CYPHER mini stent in small vessels have not been reported.

## Conclusions

In the treatment of small coronary vessels, drug-eluting stents have provided consistently improved outcomes compared with bare metal stents across different stent platforms and antirestenotic drugs. The safety and performance of the TAXUS paclitaxel-eluting stent have been demonstrated with preclinical, clinical trial, and registry data. In particular, the improved design of the second-generation, thin-strut 2.25 mm TAXUS Liberté Atom stent compared with the 2.25 mm TAXUS Express Atom stent results in less revascularization over time, without increasing mortality or myocardial infarction. A third-generation stent, TAXUS Element™, is currently being investigated for use in small vessels in the PERSEUS (A Prospective Evaluation in a Randomized Trial of the Safety and Efficacy of the Use of the TAXUS® Element™ Paclitaxel-Eluting Coronary Stent System for the Treatment of De Novo Coronary Artery Lesions) Small Vessel trial and has demonstrated 12-month superiority in efficacy to the bare metal Express stent control.[59,60]

## Disclosure

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