JACC: CARDIOVASCULAR INTERVENTIONS VOL. 3, NO. 4, 2010

ISSN 1936-8798/10/$36.00
PUBLISHED BY ELSEVIER INC. DOI: 10.1016/j.jcin.2009.12.015

A Novel Paclitaxel-Eluting Stent With an Ultrathin Abluminal Biodegradable Polymer

9-Month Outcomes With the JACTAX HD Stent

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Objectives The JACTAX HD trial ("JACTAX" Trial Drug Eluting Stent Trial) evaluated the safety and clinical performance of a novel JACTAX HD (Boston Scientific Corporation, Natick, Massachusetts) paclitaxel-eluting stent (PES) in de novo coronary lesions.

Background The JACTAX HD (Boston Scientific) stent consists of a pre-crimped bare-metal Liberté (Boston Scientific) stent coated on its abluminal aspect with an ultrathin (<1 μm) 1/1 mixture of biodegradable polylactide polymer and paclitaxel applied as discrete microdots (nominal totals of 9.2 μg each of polymer and paclitaxel per 16-mm stent).

Methods In this prospective, single-arm, multicenter, first-human-use study (n = 103), the primary end point of 9-month major adverse cardiac events (MACE) (cardiac death, myocardial infarction, ischemia-related target vessel revascularization) was compared with an objective performance criterion (OPC) of 17% (11% MACE based on TAXUS ATLAS [TAXUS Liberté-SR Stent for the Treatment of de Novo Coronary Artery Lesions] trial results plus a pre-specified noninferiority margin of 6%).

Results The composite primary end point occurred in 7.8% of JACTAX HD patients with an upper 1-sided 95% confidence limit of 13.6%, thus meeting the pre-specified criteria for noninferiority. There was no death, Q-wave myocardial infarction, or stent thrombosis through 9 months. In-stent late loss was 0.33 ± 0.45 mm, with an in-stent binary restenosis of 5.2% and net volume obstruction by intravascular ultrasound of 11.4 ± 11.2%.

Conclusions The JACTAX HD stent with an abluminal biodegradable polymer showed 9-month MACE, in-stent late loss, restenosis, and net volume obstruction comparable to that observed with the TAXUS Liberté (Boston Scientific) stent coated with a conformal durable polymer. Further studies are underway to better evaluate the potential of this new PES design, which might allow for more rapid endothelialization and improved vessel healing. ("JACTAX" Trial Drug Eluting Stent Trial; NCT00754728) (J Am Coll Cardiol Intv 2010;3:431–8) © 2010 by the American College of Cardiology Foundation

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Manuscript received August 7, 2009; revised manuscript received November 30, 2009, accepted December 13, 2009.

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APRIL 2010:431–8

Drug-eluting stents (DES) that facilitate controlled local release of antiproliferative drugs from a durable polymer delivery system have been shown to significantly reduce angiographic restenosis compared with bare-metal stents (BMS) (1–4). The associated reduction in subsequent repeat revascularization confers no significant difference in death or myocardial infarction (MI) (5), but some data suggest that DES such as the sirolimus-eluting (SES) CYPHER (Cordis Corporation, Miami Lakes, Florida) stent and the paclitaxel-eluting (PES) TAXUS (Boston Scientific Corporation, Natick, Massachusetts) stent might increase the risk of late stent thrombosis (LST) (5,6) due to delayed arterial healing with incomplete re-endothelialization and/or a chronic inflammatory response (7–9). Several major medical societies (including the American Heart Association, American College of Cardiology, and Society for Cardiac Angiography and Interventions) now recommend that dual antiplatelet therapy (DAPT) (thienopyridine and aspirin) be taken for at least 1 year after DES implantation, if tolerated, to protect against possible stent thrombosis (ST) (10,11). The DAPT study is evaluating whether longer (30 months vs. 12 months) DAPT might be required (12).

To maintain the antiproliferative effect of conventional DES while allowing timelier and more complete re-endothelialization (and hopefully minimize LST risk and the required duration of DAPT), several manufacturers are testing DES with abluminally applied biodegradable polymers that leave a polymer-free BMS after drug release is complete. Clinical results have been variable. In the randomized first-human-use (FHU) FUTURE I (First Use To Underscore restenosis Reduction with Everolimus) trial, an everolimus-eluting stent with a continuous abluminal coating of the bioabsorbable polymer polylactic acid demonstrated significantly less 6-month in-stent late loss than its BMS control, with comparable 12-month clinical outcomes (13). Similarly, in the randomized FHU STEALTH (Stent Eluting A9 BioLimus Trial in Humans) trial, a polylactic acid biolimus-eluting stent showed significant efficacy in reducing 6-month late loss and percent diameter stenosis (DS) with clinical safety equivalent to the control BMS (14). The subsequent randomized LEADERS (Limus Eluted from a Durable versus Erodable Stent Coating) trial further showed this stent design was angiographically and clinically noninferior to the CYPHER stent (15). The use of discrete reservoirs located within the stent strut and filled with a drug-polymer mixture has also been tested. In the nonrandomized, open-label PISCES (Paclitaxel In-Stent Controlled Elution Study), paclitaxel released from a poly–lactic-co-glycolic acid polymer showed good inhibition of neointimal hyperplasia in long-duration abluminal release (16); similar results were seen in the EuroSTAR (European Cobalt Stent with Antiproliferative for Restenosis) registry (17). In the subsequent large, randomized, controlled COSTAR (Cobalt Chromium Stent With Antiproliferative for Restenosis) II study, however, this stent was found to be inferior to TAXUS (18).

The JACTAX HD stent represents a novel way to accomplish abluminal coating, with neither continuous polymer nor filled wells penetrating stent struts. Instead, a pre-crimped bare-metal Liberté (Boston Scientific Corporation) stent is abluminally coated with a minimal amount of biodegradable polylactide polymer plus paclitaxel (nominally 9.2 μg of each per 16-mm stent) applied to the abluminal surface as 2,750 discrete microdots/16-mm stent (Fig. 1). The coating drops impact the stent at high velocity, allowing the low viscosity solution to spread in a thin layer and adhere to the stent surface. At $\leq$1 μm, the polymer thickness provided by this approach is approximately 15-fold thinner than that of TAXUS Liberté (Boston Scientific Corporation). The biodegradable polymer is designed to fully release drug in 60 days and resorb in 4 months, thereby eliminating chronic exposure to drug and polymer. The concept of the JACTAX HD (Boston Scientific) stent is thus to emulate a DES initially and then transition to a BMS. The JACTAX HD trial ("JACTAX" Trial Drug Eluting Stent Trial) evaluated safety and clinical performance of the JACTAX HD stent in de novo coronary lesions. We report here the 9-month outcomes.

Abbreviations and Acronyms

BMS = bare-metal stent(s)
CI = confidence interval
DAPT = dual antiplatelet therapy
DES = drug-eluting stent(s)
DS = diameter stenosis
FHU = first-human-use
IVUS = intravascular ultrasound
LST = late stent thrombosis
MACE = major adverse cardiac events
MI = myocardial infarction
OCT = optical coherence tomography
OPC = objective performance criterion
PES = paclitaxel-eluting stent(s)
QCA = quantitative coronary angiography
SES = sirolimus-eluting stent(s)
ST = stent thrombosis
TLR = target lesion revascularization
TVR = target vessel revascularization

Methods

Device description. The JACTAX HD stent is illustrated in Figure 1. The coating is exclusively abluminal with minimal amounts of paclitaxel in a low molecular weight biodegradable polylactide polymer; 3 sides of the stent strut remain devoid of drug or polymer. Drug is 100% available (no residual), and the polymer is designed to resorb completely in 4 months. Application of the polymer-drug combination on a pre-mounted stent avoids injury or distortion of the coating during the crimping process.

Study design. The prospective, single-arm, multicenter FHU JACTAX HD study (see registry information after the abstract) was designed to test whether outcomes in de

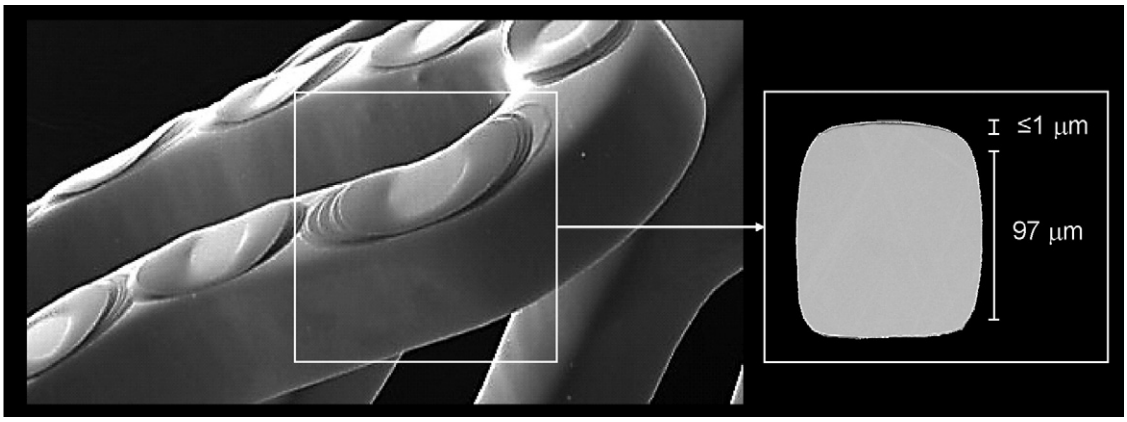

Figure 1. JACTAX HD Stent

The JACTAX HD drug-eluting stent is a Liberté stent coated with the Juxtaposed Ultrathin Abluminal Coating process, which applies paclitaxel in the low molecular weight biodegradable carrier polymer polylactide (1/1 by weight; nominally 9.2 μg of each per 16-mm stent) onto the abluminal surface of a pre-mounted stent in discrete areas (approximately 3.4 ng polymer/microdot; see **box**). Three sides of each stent strut remain bare, covered by neither polymer nor drug. Strut (97 μm) and polymer (≤1 μm) together are ≤98 μm thick.

novo coronary lesions treated with the JACTAX HD stent would be noninferior to an objective performance criterion (OPC) based on outcomes with TAXUS Liberté from the TAXUS ATLAS (TAXUS Liberté-SR Stent for the Treatment of de Novo Coronary Artery Lesions) trial (19). The primary end point was 9-month major adverse cardiac events (MACE) (defined as cardiac death, MI, and ischemia-driven target vessel revascularization [TVR]) (Online Appendix). Noninferiority was assessed by comparing the upper 95% confidence interval (CI) of the observed end point with an OPC of 17%. The OPC was based on TAXUS ATLAS results (11%) plus a pre-specified noninferiority margin of 6%, chosen to ensure that the JACTAX HD stent would have similar clinical performance to that of TAXUS Liberté.

Patient selection, procedure, and follow-up. Eligible patients (≥18 years) had a de novo lesion in a native coronary artery and clinical and angiographic indications for percutaneous coronary intervention. Key angiographic inclusion criteria were lesion length ≤20 mm, stenosis ≥70%, and reference vessel diameter of 2.75 to 3.5 mm (visual estimate). One nontarget lesion, located in a different vessel distribution, could also be treated. The nontarget lesion was to be successfully treated first with either a TAXUS Liberté PES or a BMS. Key exclusion criteria included excessive target lesion tortuosity; involvement of a side branch >2.0 mm in diameter; moderate or severe calcification of the target lesion; MI <72 h before the procedure; stroke or transient ischemic attack <3 months before the procedure; and allergy or contraindication to aspirin, clopidogrel, or stainless steel. Study enrollment occurred after successful pre-dilation of the study vessel and introduction of the JACTAX HD stent.

Patients received DAPT (150 mg aspirin plus 300 mg clopidogrel) before or immediately after the procedure. Aspirin (150 mg daily) was mandated by the protocol for 12 months and recommended indefinitely. Thienopyridine (75 mg clopidogrel daily) was mandated for 6 months and recommended for ≥12 months per local practice. Clinical follow-up was scheduled at 1 month and 4, 9, 12, and 24 months. Follow-up quantitative coronary angiography (QCA) and intravascular ultrasound (IVUS) were scheduled at 9 months.

Ethics review committees of participating institutions approved the protocol. Patients provided written informed consent before enrollment. The study was conducted under Good Clinical Practice conditions and in compliance with the medical device regulations for the participating countries (Germany and the United Kingdom). The Online Appendix lists the sponsor, core laboratories, and contract research organization managing the study.

End points and data management. The primary end point was 9-month MACE. Secondary end points included ST defined per the Academic Research Consortium definitions (20) and assessments of restenosis based on core laboratory analyses of QCA and IVUS results. Monitors independent of the sponsor verified all data from case report forms. An independent medical monitor adjudicated MACE and ST, and an autonomous data monitoring committee periodically reviewed safety data (Online Appendix).

Angiographic late loss and binary restenosis results were compared with results for a cohort of selected patients from the TAXUS ATLAS study (19). The 2 studies had similar inclusion/exclusion criteria; the main differences were lesion-based. Thus the TAXUS ATLAS comparator consisted of patients who would have met the slightly more

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Table 1. Baseline Demographic Data and Target Lesion Characteristics

	JACTAX HD (n = 103)
Patient characteristics	
Men	80.6 (83)
Age (yrs)	65.6 ± 8.9
Smoking	46.6 (48)
Stable angina	67.9 (70)
Unstable angina	19.4 (20)
Diabetes mellitus	21.4 (22)
Insulin	6.8 (7)
Hyperlipidemia	71.8 (74)
Hypertension	80.6 (83)
Previous PCI	42.7 (44)
Previous CABG	12.6 (13)
Target lesion characteristics*	
Target lesion RVD, mm	2.8 ± 0.4
Lesion length, mm	13.7 ± 5.8
Percent diameter stenosis, %	72.4 ± 10.9
Location	
Left anterior descending artery	40.8 (42)
Circumflex/obtuse marginal	31.1 (32)
Right coronary artery	28.2 (29)

Values are % (n) or mean ± SD; data shown are for the intent-to-treat population. *Core laboratory analysis.
CABG = coronary artery bypass graft; PCI = percutaneous coronary intervention; RVD = reference vessel diameter.

restrictive JACTAX HD lesion criteria (site reported lesion length ≤20 mm, percent DS ≥70 mm, and reference vessel diameter of 2.75 to 3.5 mm).

Statistical methods. The analysis sample for the primary end point was the intent-to-treat population. Patient, lesion, and procedural characteristics and event rates were analyzed with descriptive statistics with SAS version 9.1 or higher (SAS Institute, Inc., Cary, North Carolina). Simple proportions with 95% CIs were used for categorical variables; continuous data are provided as mean ± SD and/or median with interquartile range.

The statistical objective of the trial was to achieve a precision of 6% on the estimate for the 9-month composite MACE rate with a 1-sided 95% CI. The MACE rate was estimated to be 11.0% on the basis of results obtained with the TAXUS Liberté stent in the TAXUS ATLAS trial (19). A sample size of 100 patients was determined necessary, with exact calculations based on the binomial distribution (21), to produce a 95% CI (PASS 2005 Power and Sample Size Software, NCSS Statistical Software, Kaysville, Utah). Thus, noninferiority of JACTAX HD to TAXUS Liberté was determined by comparing the 1-sided 95% upper confidence bound of the observed 9-month MACE rate (calculated by the Clopper-Pearson exact method) with an OPC of 17% (11% plus the pre-specified margin of 6%). Statistical significance was determined with the exact 1-sided p value of the binomial test for the study hypothesis; $p < 0.05$ was considered significant.

Results

Patient, lesion, and procedural characteristics. The JACTAX HD study enrolled 103 patients at 5 sites in Germany and England (Online Appendix). Baseline demographic data and target lesion characteristics are shown in Table 1. There were 127 lesions treated, including 24 nonstudy lesions; 110 devices were implanted to treat 103 target lesions in 103 patients. Device technical success, defined as successful delivery and stent deployment, was 99.1% (109 of 110, 1 geographical miss). Lesion success, defined as successful stent delivery and deployment to the intended lesion location with Thrombolysis In Myocardial Infarction flow grade 2 to 3 and DS ≤30% by QCA, was 99.0% (102 of 103, 1 patient with 30.7% DS). Procedural success (lesion success with no MACE through discharge) was 97.1% (100 of 103, 1 case with lesion failure and 2 patients with non–Q-wave MI).

Clinical outcomes at 30 days and 9 months. Clinical outcomes are shown in Table 2. The composite primary end point occurred in 7.8% of patients and consisted of 2 non–Q-wave MIs and 6 ischemia-driven TVRs, of which 2 were target lesion revascularizations (TLRs). The upper 1-sided 95% CI of the primary end point, calculated by the Clopper-Pearson exact method, was 13.6%. This value was below the control comparator of 17% (OPC based on the TAXUS ATLAS trial result of 11% plus the pre-specified margin of 6%), thereby indicating noninferiority of the JACTAX HD to TAXUS Liberté stent ($p = 0.006$ for noninferiority). The total TVR rate (including ischemia-driven and non–ischemia-driven events) was 10.7% (n = 11), of which 4.9% (n = 5) were adjudicated as TLR. There was no death, Q-wave MI, or ST through 9 months.

Table 2. Clinical Outcomes at 30 Days and 9 Months

	30 Days (n = 103)	9 Months (n = 103)
All death	0.0 (0)	0.0 (0)
Major adverse cardiac events*	1.9 (2)	7.8 (8)
Cardiac death	0.0 (0)	0.0 (0)
Myocardial infarction	1.9 (2)	1.9 (2)
Q-wave	0.0 (0)	0.0 (0)
Non–Q-wave	1.9 (2)	1.9 (2)
TVR, ischemia driven	0.0 (0)	5.8 (6)
TLR	0.0 (0)	1.9 (2)
Nontarget lesion TVR	0.0 (0)	3.9 (4)
Stent thrombosis†	0.0 (0)	0.0 (0)

Values are % (n); data are binary rates. *Includes cardiac death, myocardial infarction, and ischemia-driven target vessel revascularization (TVR). †Definite plus probable per Academic Research Consortium definitions (20).
TLR = target lesion revascularization.

QCA and IVUS results. Table 3 shows results of QCA (n = 97) and 3-dimensional IVUS (n = 62) paired lesion analyses. At 9 months, in-stent binary restenosis was 5.2% and in-stent late loss was 0.33 ± 0.45 mm. The cumulative frequency distribution of angiographic in-stent late loss for JACTAX HD was comparable to that observed in similar matched patients selected from the TAXUS ATLAS trial (19) (Fig. 2). The data distribution was somewhat skewed in both groups, and Figure 3 shows the median and interquartile range for in-stent and in-segment late loss. Binary restenosis was also similar for the 2 groups (Fig. 4). Two patients (3.2%) had incomplete stent apposition immediately after stent placement and at 9-month follow-up; no cases of late incomplete apposition were observed. Mean net volume obstruction by IVUS was 11.4 ± 11.2%; the median was 8.5% with 25th and 75th percentiles of 1.3% and 18.4%, respectively.

Discussion

This FHU study evaluated safety and clinical performance of the novel JACTAX HD stent, which consisted of a pre-crimped bare-metal Liberté stent with an abluminal coating of paclitaxel in an ultrathin biodegradable polymer applied as a controlled pattern of microdots. The JACTAX coat weight (<20 μg) is <10% of that of other abluminal stents with biodegradable polymers in current clinical testing. Safety and efficacy of the JACTAX HD stent compared well with an OPC based on TAXUS ATLAS patients treated with TAXUS Liberté (19). The observed 9-month composite MACE rate of 7.8% had a 1-sided upper 95% confidence bound of 13.6%, which was significantly (p = 0.006) below the 17% noninferiority boundary. This demonstrates noninferiority (equivalence or better) of the JACTAX HD stent to the TAXUS Liberté stent in this composite of safety and efficacy events, with no episodes of death, Q-wave MI, or ST through 9 months.

Similarly, late loss with JACTAX HD (0.33 ± 0.45 mm in-stent; 0.14 ± 0.39 mm in-segment) was comparable to or better than that observed with TAXUS EXPRESS or TAXUS Liberté in numerous prior clinical trials (2,18,19,22–24). This measure of efficacy was also con-

Table 3. JACTAX HD Quantitative Coronary Angiography and 3D IVUS Paired Lesion Analyses

Quantitative Coronary Angiography			
Parameter	**Pre-Procedure (n = 97)**	**Post-Procedure (n = 97)**	**9 Months (n = 97)**
RVD	2.78 ± 0.43	2.80 ± 0.42	2.75 ± 0.44
MLD (in stent), mm	—	2.60 ± 0.37	2.27 ± 0.57
MLD (in segment), mm	0.78 ± 0.35	2.19 ± 0.45	2.05 ± 0.54
Percent DS (in stent)	—	6.73 ± 9.09	17.66 ± 15.84
Percent DS (in segment)	72.32 ± 11.01	21.91 ± 9.60	25.86 ± 13.57
Late loss (in stent)	—	—	0.33 ± 0.45
Late loss (in segment)	—	—	0.14 ± 0.39
Binary restenosis (in stent)	—	—	5.15%
Binary restenosis (in segment)	—	—	6.19%
3D IVUS			
Parameter	**Index Procedure (n = 62)**		**9 Months (n = 62)**
Stent volume, mm^3	149.1 ± 52.5		157.7 ± 64.0
Lumen volume, mm^3	149.1 ± 52.6		140.9 ± 60.5
Malapposition	3.2 (2)		3.2 (2)
Neointimal volume, mm^3	—		17.6 ± 18.3
Net volume obstruction, %	—		11.4 ± 11.2

Data are mean ± SD, %, or % (n).
DS = diameter stenosis; IVUS = intravascular ultrasound; MLD = minimal lumen diameter; RVD = reference vessel diameter; 3D = 3-dimensional.

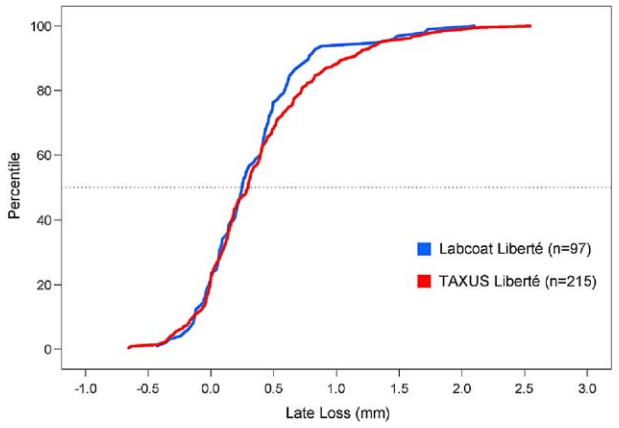

Figure 2. Cumulative Frequency Distribution of In-Stent Late Loss: JACTAX HD and TAXUS ATLAS Patients at 9 Months

The TAXUS ATLAS patient cohort is described in the Methods section.

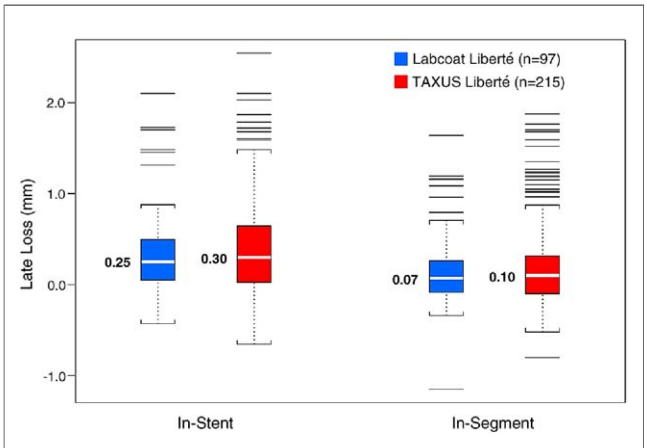

Figure 3. Late Loss in JACTAX HD and TAXUS ATLAS Patients at 9 Months

The figure shows the median and interquartile range and the skewed data distribution in both groups.

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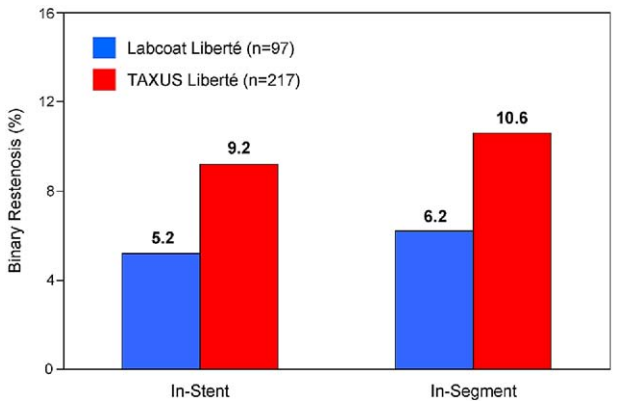

Figure 4. Binary Restenosis in JACTAX HD and TAXUS ATLAS Patients at 9 Months

The figure shows comparable results for binary restenosis between the JACTAX HD group and a matched patient cohort selected from the TAXUS ATLAS trial (described in the Methods section).

firmed by the low neointimal hyperplasia volume percentage of 11.4 ± 11.2% by IVUS and by the low rate of clinical TLR (1.9% at 9 months).

These results show that an ultrathin abluminal biodegradable approach can match the performance of a conventional TAXUS stent with a thicker conformal permanent polymer coating and significantly higher drug dose. Release of sirolimus from a polymer reservoir was recently shown to be superior to TAXUS in the NEVO RES-ELUTION I (A Randomized, Multi-Center, Single-Blind Comparison of the Conor Cobalt Chromium Reservoir Based Stent With Sirolimus Elution Versus the TAXUS Liberté Paclitaxel-eluting Coronary Stent System in De Novo Native Coronary Artery Lesions) trial with a primary end point of 6-month late loss (25). This contrasts with clinical outcomes in the COSTAR II trial where reservoir-based abluminal release of paclitaxel was shown to be inferior to TAXUS (18).

The use of polymer-free DES platforms has also been investigated clinically, with mixed results. The randomized ELUTES (European evaLUation of pacliTaxel Eluting Stent), ASPECT (Asian Paclitaxel-Eluting Stent Clinical Trial), and DELIVER trials compared BMS with abluminally coated, polymer-free paclitaxel stents. In the ELUTES trial, the highest-dose PES showed significantly less 6-month late loss with comparable 12-month clinical results (26). In the ASPECT trial, the highest-dose PES showed significantly less 6-month in-stent neointimal hyperplasia, but that advantage was lost to late "catch-up" by 2 years (27). Among DELIVER patients with angiographic follow-up, 8-month in-stent late loss was significantly less, but there was no significant difference in the primary end point of target vessel failure or the secondary end point of binary restenosis (28). The polymer-free sirolimus-eluting ISAR stent showed similar late loss versus TAXUS in the randomized ISAR-TEST (Rapamycin-Eluting Stents With Different Polymer Coating to Reduce Restenosis) trial (29) but failed to show noninferiority when compared with the CYPHER stent (30). More recently, in the randomized ISAR-TEST-2 trial, a dual-DES with sirolimus and the antirestenotic agent probucol showed significantly less late loss at 6 to 8 months versus the polymer-based zotarolimus-eluting stent but was comparable to the CYPHER stent (31).

Although the JACTAX HD late loss efficacy data are comparable to that of the TAXUS stent, there is no direct proof in this study that this approach provides more rapid, complete, or functional endothelial coverage to potentially reduce the risk of very late ST (>1 year) (6–9,32,33) or shorten the duration of required DAPT. Optical coherence tomography (OCT) imaging can provide some assessment of endothelial coverage. In 34 SES patients (57 stents), Matsumoto et al. (34) found that at 6 months only 16% showed complete stent strut coverage. Takano et al. (35) reported that, at 3-month follow-up, 95% (20 of 21) of SES patients had some exposed struts (n = 31 SES). On a per-strut basis, the rate of exposed struts was 15%, of which 6% were exposed with malapposition. These rates were significantly higher in acute coronary syndrome lesions (35). The 15% frequency of exposed struts at 3 months decreased to 5% at 2 years, but the difference was not statistically significant (36). In a randomized trial comparing SES with and without polymer (n = 12/group), mean neointimal thickness at 90 days was significantly less for the polymer-coated stent, but more struts were uncovered (>10% vs. <3%, respectively) (37). Previous studies have suggested that >30% uncovered struts/cross-section might correlate with the occurrence of LST (8).

Studies are underway to better evaluate the potential for more rapid endothelialization and improved vessel healing with the JACTAX HD stent, but a preliminary ad hoc OCT analysis (20 μm resolution) of 13 patients at 1 center in this study found most examined struts covered at 9 months (38). Further OCT assessment of vascular response to the JACTAX HD stent is ongoing in the Optical Coherence Tomography Drug Eluting Stent Investigation (NCT00776204), which will evaluate the extent of strut coverage and malapposition with JACTAX versus TAXUS Liberté in de novo coronary lesions at 6 months in 60 patients with high-resolution (approximately 10 to 15 μm axial) OCT. Larger clinical studies with long-term follow-up, however, will be necessary to determine whether use of the JACTAX HD stent results in reduced very late ST rates, providing a potential opportunity to reduce the need for DAPT.

Study limitations. Limitations of this study include the small number of patients with relatively simple lesions, typical of an FHU study, together with the absence of a randomized control group.

Conclusions

The results of the JACTAX HD trial show that the novel JACTAX HD stent with an ultrathin abluminal coating of discrete microdots of paclitaxel mixed with drug delivery controlled by a biodegradable polymer can provide safety and effectiveness end points comparable to those achieved with the conventional conformal durable polymer TAXUS Liberté stent. Further studies are underway to more rigorously evaluate this potential for the JACTAX design to allow more rapid endothelialization and potentially reduce the requirement for prolonged DAPT.

Acknowledgments

The authors thank Carola Alfaro, MS, and Alex Shih, PhD, (Boston Scientific Corporation) for statistical analysis and Ruth M. Starzyk, PhD, and Donald S. Baim, MD, (Boston Scientific Corporation) for assistance with drafting and editing the manuscript.

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Key Words: biodegradable polymer ■ coronary restenosis ■ drug-eluting stent.

APPENDIX

For additional definitions and lists of study participants, please see the online version of this article.