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First in man evaluation of a sirolimus-eluting stent with abluminal fluoropolymeric/triflusal coating with ultrathin struts by OCT at 9 months follow up. The PROMETHEUS study

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ABSTRACT

Objectives: We sought to investigate stent healing and neointimal hyperplasia with ihtDESTiny drug-eluting stent (DES) by optical coherence tomography (OCT) examination conducted 9 months after implantation.
Background: The currently used DES present certain features that have been linked separately to their better performance in terms of efficacy and safety.
Methods: First-in-man, prospective and multicenter study including patients treated with ihtDESTiny stent undergoing OCT examination at 9 months follow up. The ihtDESTiny stent is a sirolimus eluting stent with an oval shape ultrathin struts (68 μm) and an abluminal coating of a fluoropolymer containing the antiplatelet agent triflusal. Primary endpoint was the percentage of obstruction of the in-stent volume by the neointima.
Results: In 58 patients (63 lesions) in-stent late lumen loss was 0.11 ± 0.23 mm (95% CI 0.05–0.16) with only in 6% of stents being > 0.5 mm and in-segment binary stenosis was 1.6%. In OCT mean neointima volume obstruction was 10.5 ± 6.9% with a mean neointima thickness of 110.9 ± 89.8 μm. The proportion of uncovered struts was 2.5%, malapposed struts 1.1% and malapposed/uncovered struts 0.7% and no subclinical thrombi detected. Mean incomplete stent apposition area was 0.1 ± 0.1 mm^2. At 12 months target lesion revascularization rate was 3% and no stent thrombosis was reported.
Conclusions: In this study the ihtDESTiny stent has shown a very low degree of neointimal proliferation associated with a low rate of uncovered/malapposed struts and total absence of subclinical thrombi at 9 months follow up.

1. Introduction

The use of drug-eluting stents (DES) has essentially supplanted the use of bare metal stents in the last years. The superior efficacy and safety shown by DES in all anatomical and clinical settings compared to bare metal stents explain this important change [1,2].

The currently used DES present certain features that have been linked to their better performance in terms of efficacy and safety [3]. Research has shown that the thinner the strut, the better the endothelialisation and so, the lower the thrombogenicity [4]. Stents with thinner struts are more flexible, which enhances their trackability and crossability. In addition stent strut thickness has been identified as an independent predictor of in-stent restenosis and thinner struts are associated with significant reduction in ST and myocardial infarction compared with thicker struts [5,6]. In addition to strut thickness, a streamlined strut compared with a square shaped cross-section strut enhances endothelisation and reduces thrombus formation [7]. Among all the polymers used in drug eluting stent designs the fluoropolymers have shown to provide the highest thromboresistance, eliciting minimal inflammation and facilitating fast and functional

Abbreviations: DES, drug-eluting stents; EES, everolimus-eluting stents; LLL, late lumen loss; OCT, optical coherence tomography; PCI, percutaneous coronary intervention; TLR, target lesion revascularization; ZES, zotarolimus-eluting stents.

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endothelialization [8–11]. The first drug eluting stent incorporating this polymer has shown the lowest rate of stent thrombosis within 2 years of implantation [12]. Regarding the strut coating, a study conducted in swines demonstrates that termination of reactive inflammation is accelerated after abluminal coating stent versus implantation of conformal coating stent [13]. Finally, all current DES use the family of –limus drugs which are superior to any other tested drugs for DES in efficacy and safety.

The ihtDEStiny ™ stent is an open-cell ultrathin cobalt-chromium sirolimus eluting stent. The coating consists in an abluminal dual layer with a fluoropolymer containing the platelet aggregation inhibitor triflusal.

In this study we sought to investigate stent healing and vascular responses with ihtDEStiny stent, as well as accurate quantification of neointimal hyperplasia after stent implantation by means of an optical coherence tomography examination conducted 9 months after implantation.

2. Methods

First-in-man, prospective and multicenter study of patients with significant coronary stenosis treated with ihtDEStiny stent undergoing angiographic follow-up and examination with OCT at 9 months after the procedure.

2.1. Population

Patients with coronary artery disease and clinical indication for percutaneous revascularization were included under the following selection criteria.

Inclusion criteria: a) Patients older than 18 years of age with an indication for percutaneous revascularization with a stent over de novo significant coronary lesions. b) Lesions located in vascular segments of at least 2.5 mm in diameter and no longer than 20 mm in length. c) The patient has no contraindication to use of double antiplatelet therapy for at least 9 months with aspirin and thienopyridines. d) The patient gives informed consent.

Exclusion criteria: a) Cardiogenic Shock; b) ST elevated myocardial infarction; c) Lesions that are chronic total occlusions, ostial, bifurcations, severely calcified or presenting thrombus, ulceration or dissection. d) Restenotic lesions, lesions located in left main coronary artery or in saphenous or mammary grafts.

All patient data, baseline and follow-up, were collected in an electronic database designed specifically for the study in which a complete anonymization of the data was guaranteed.

Clinical follow up after the index procedure included outpatient clinical visits and telephone contact at 6 and 12 months. Angiographic follow up was scheduled at 9 months ± 15 days after PCI. Clinical events were evaluated and adjudicated by an independent events committee of 2 cardiologists not involved in the study which requested clinical information to the investigators when needed. A Contract Research Organization was in charge of the monitorization process.

The study was approved by the clinical research committees of each participating institution. All patients provided informed consent for participation.

2.2. The ihtDEStiny stent

The ihtDEStiny™ stent (IBERHOSPITEX S.A., Lliça de Vall, Spain) is an open-cell ultrathin cobalt-chromium sirolimus (0.9 μg/mm^2) eluting stent with an oval shape strut with a thickness of 68 μm (Fig. 1). The stent geometry is based in the forth generation of IHT coronary stent platform with unique offset mid-strut connectors arranged in an helicoidal pattern and a unique heat treatment to balance radial strength and longitudinal stability. The oval structure was accomplished by using a 4 axis laser cutting stent system, preferentially fempto laser and a special electropolishing system. The coating consists in an abluminal dual layer (base plus barrier layer) with a biostable fluoropolymer containing a platelet aggregation inhibitor of the salicylate family, the triflusal. Triflusal is covalently bonded to the polymer and its delivery is guided by hydrolysis. Due to the high hydrophobicity of the polymer, the drug is steadily released within the following 24 months after implantation. The drug is covalently linked to the polymer to ensure the highest posible drug content and delivery timeframe extension. Available diameters range 2.0–4.0 mm and available lengths range 8–40 mm.

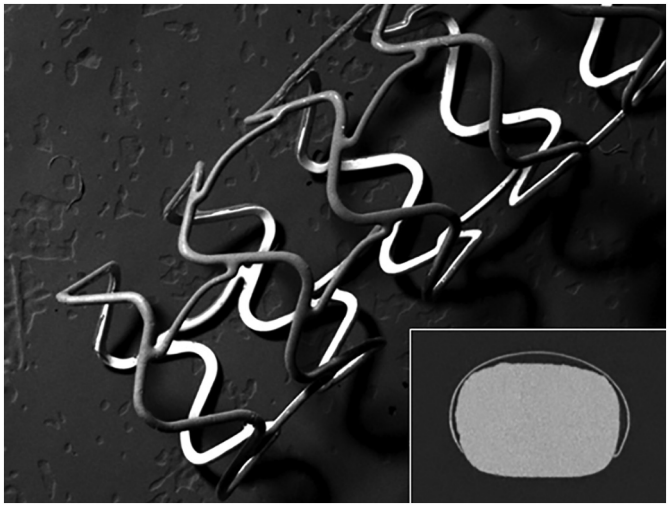

Fig. 1. Scanning electron microscopy showing the stent platform with an open cell design and cross-section of the struts. Magnification of the main image (SE1/10kV/35×) and minor image (BSE). Images are acquired using an EVO SEM (Carl Zeiss, Germany).

2.3. Procedure

During the index procedure, all lesions were treated with the ihtDEStiny stent. Plaque preparation techniques, the use of intravascular imaging, and optimization of the result with postdilatation were all at the discretion of the operator. The selected stent length should guarantee full coverage of the lesion. Only patients with a single index revascularization procedure were included, in which all lesions the operator considered significant would be treated. Cardiac enzymes measurement after PCI was not protocolized and was left to the discretion of the clinicians in charge who decided according to the procedural results, symptoms and electrocardiographic changes.

The patients were treated before the procedure with one or two antiplatelet agents at the appropriate doses, according to clinical indication and at the discretion of the cardiologist in charge of the patient. After the procedure, double antiplatelet therapy was maintained for at least 9 months and subsequently a single antiplatelet agent was left indefinitely.

2.4. Angiographic analysis

Angiographic analysis was performed by a dedicated core-laboratory (BARCICORE-lab, Barcelona, Spain) using specific software for quantitative coronary angiography analysis (QAngio XA 7.3 version; Medis, the Netherlands) according to standard procedures. Angiographic analysis was conducted at baseline, immediately after PCI and at 9 months follow up.

The following formulas provide the measured parameters: (1) diameter stenosis = (reference diameter − minimal lumen diameter)/reference diameter; (2) acute lumen gain = post-PCI minimal lumen

diameter − baseline minimal lumen diameter; (3) late lumen loss = post-PCI minimal lumen diameter − follow-up minimal lumen diameter.

2.5. OCT acquisition at follow up and offline analysis

Per protocol OCT acquisition was planned at 9-month angiographic follow-up with a variation of ±15 days. All OCT recordings were collected for analysis in a centralized Core Lab (BARCICORE-lab, Barcelona, Spain).

Investigators used the currently available optical frequency domain imaging systems (Ilumien or Optis Imaging System™, St Jude Medical, US or the Lunawave Imaging System™, Terumo, Japan) with a pullback speed ranging from 18 to 20 mm/s. The monorail imaging catheter was advanced distal to the stented segment. Images were acquired using a non-occlusive technique with a contrast infusion. The optimal volume/time intracoronary infusion of contrast was tested to achieve a complete blood clearance in the vessel lumen. In case of restenosis, the examination with OCT was done first and then treatment or not was applied according to operator's decision.

Qualitative and quantitative OCT analyses were performed by a dedicated core-laboratory using specific software for analysis (QIVUS Research edition 3.1 version, Medis, the Netherlands). Two blinded analysts were requested to assess the following qualitative OCT findings in the entire pullback (0.2 mm intervals): the neointima pattern at the cross-section with largest neointima area and neoatherosclerotic plaques. Neointima pattern was classified as homogeneous, heterogeneous and layered at the cross-section with largest neointima. Cases with insufficient neointima to evaluate the tissue pattern were classified as absent neointima. Neoatherosclerotic plaques were defined as the observation of a fibroatheroma or fibrocalcific plaques within the neointima tissue with a longitudinal extension of ≥1 mm. Fibroatheroma plaques were characterized as signal-poor regions with high signal-attenuation and diffuse borders. Fibrocalcific plaques were defined as signal-poor regions with low signal attenuation and clear plaque borders.

Quantitative OCT data was analysed each 1-mm. In summary, the software drew the lumen and stent contours automatically. Manual corrections were performed if necessary. The neointima thickness was automatically calculated from all the stent struts as the distance between the inner center strut to the lumen perimeter. Taking into account the strut thickness of the study device and the axial resolution of the OCT technique, malapposed struts were defined as those with a distance between the inner center strut to lumen perimeter ≥90 μm. Intimal hyperplasia volume was calculated as stent volume minus lumen volume. To eliminate the possible influence of vessel size, the percentage of stent obstruction was calculated as intimal hyperplasia volume/stent volume x 100.

2.6. Endpoints and definitions

Primary endpoint: Percentage of obstruction of the in-stent volume by the neointima at 9 months after implantation.

Secondary endpoints: 1)% of struts covered 9 months after implantation; 2)% of malapposed struts 9 months after implantation; 3) Late lumen loss and binary restenosis by quantitative angiography at 9 months after implantation; 4) Incidence of device related cardiac events (cardiac death, target vessel myocardial infarction and target lesion revascularization) at 12 months after implantation.

Death was regarded as cardiac in origin unless an obvious non-cardiac cause could be identified. Myocardial infarction was defined according to the fourth Universal Definition by the European Society of Cardiology and the American College of Cardiology Foundation. Target lesion revascularization (TLR) was defined as either repeat percutaneous or surgical revascularization for a lesion anywhere within the stent or the 5-mm borders proximal or distal to the stent. Stent thrombosis was defined according to the Academic Research Consortium criteria. Device success was defined as the attainment at the target site of a final residual diameter stenosis of less than 30% with a TIMI III flow using only the assigned study device.

2.7. Statistics

The reported standard deviation for the percentage of obstruction with current DES is 6–8% and the mean value 10–20%, so we hypothesized that the difference of means considered to be significant for this endpoint could be 3.5% [14,15]. Assuming an α-level of 0.05 and a β-level of 0.20 (power is 80%), then the sample for this study should be at least of 55 stents to be examined with OCT in follow up. In addition, based on published meta-analysis of OCT studies evaluating stent healing and vascular response characteristics [16], a 50 patient (at least 60 lesions) study should provide sufficient power to demonstrate neointimal stent volume obstruction, strut coverage, and apposition characteristics of the ihtDEStiny DES. Based on the aforementioned considerations and expecting a 10–15% loss to imaging follow-up rate, we thus planned to enroll a minimum of 60 patients.

Continuous variables are presented as mean ± standard deviation or median (interquartile range) and categorical variables as percentages. Distribution was assessed for each variable with the Kolmogorov-Smirnov test.

3. Results

A total of 65 patients with 73 target lesions were included. The clinical characteristics are listed in Table 1. These patients wre 60 years of age in average, with frequent antecedents of myocardial infarction and PCI. In 74% of cases the indication for PCI was an acute coronary syndrom. Procedural details are provided as well in Table 1. Stent length was 20 ± 5 mm and stent diameter 3.1 ± 0.36 mm with usage of intravascular imaging in 7 patients (10.7%). Device success was 100%. Post-procedural myocardial necrosis was detected in 1 patient (1.5%).

Angiographic and OCT examination at 9 months was finally done in 58 patients (63 target lesions) since 6 patients declined the invasive

Table 1
Clinical and procedural characteristics.

	N = 65
Age, years	60 ± 10
Women	14 (21.5%)
Hypertension	42 (64.6%)
Diabetes	14 (21.5%)
Dyslipidemia	45 (69.2%)
Smoker	32 (49.2%)
Chronic renal failure	4 (6.1%)
Previous MI	16 (24.6%)
Previous PCI	17 (26.1%)
Previous CABG	1 (1.5%)
Ejection fraction, %	57 ± 9
Stable angina	17 (26.1%)
Unstable angina	21 (32.3%)
Non ST elevated MI	27 (41.5%)
Radial access	64 (98.5%)
Number lesions treated	1.1 ± 0.4
Left anterior descending	32 (49.2%)
Left circumflex	17 (26.1%)
Right coronary artery	16 (24.6%)
Stent length, mm	20 ± 5.4
Stent diameter, mm	3.1 ± 0.36
Intravascular imaging	7 (10.7%)
Device success	65 (100%)
DAPT time, months	11.3 ± 2

CABG: coronary artery bypass grafting; DAPT: dual antiplatelet therapy; MI: myocardial infarction; PCI: percutananeous coronary intervention.

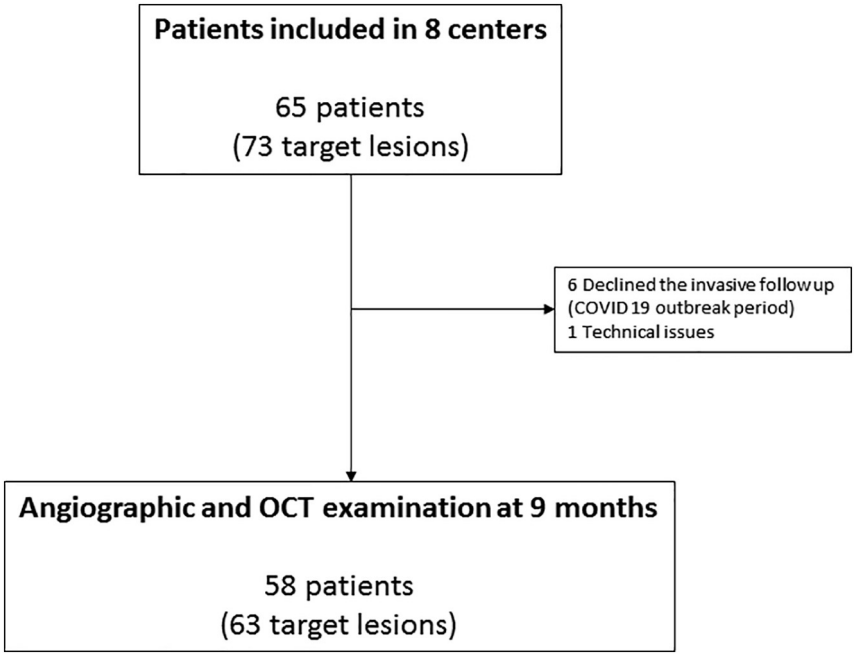

Fig. 2. Flow chart of the study.

follow up (during COVID 19 outbreak period) and in 1 patient a technical issue prevented to perform the procedure. The flow chart of the study is presented in Fig. 2.

The angiographic analysis is presented in Table 2. At 9 months, in-stent analysis showed a late lumen loss of 0.11 ± 0.23 mm (95% CI 0.05–0.16), a diameter stenosis of 12.69 ± 8.35% and no binary stenosis >50% was observed. In-segment analysis showed diameter stenosis of 21.28 ± 9.47% with a binary stenosis >50% in 1.6%. The in-stent late lumen loss distribution is presented in Fig. 3. Only in 6% of stents the late lumen loss was >0.5 mm.

Table 2
Quantitative angiographic data at baseline and 9 months follow up.

	Lesions (n=63)
Pre-intervention	
Lesion length, mm	11.74 ± 3.96
Reference vessel diameter, mm	2.78 ± 0.50
Minimal lumen diameter, mm	1.05 ± 0.42
Diameter stenosis, %	61.98 ± 14.12
Post-intervention (in-stent)	
Reference lumen diameter, mm	2.92 ± 0.39
Minimal lumen diameter, mm	2.63 ± 0.37
Diameter stenosis, %	9.85 ± 4.58
Post-intervention (in-segment)	
Reference lumen diameter, mm	2.86 ± 0.45
Minimal lumen diameter, mm	2.25 ± 0.43
Diameter stenosis, %	21.31 ± 9.21
9-month follow-up (in-stent)	
Reference lumen diameter, mm	2.89 ± 0.35
Minimal lumen diameter, mm	2.52 ± 0.39
Late lumen loss, mm	0.11 ± 0.23
Diameter stenosis, %	12.69 ± 8.35
Binary stenosis (DS> 50%), n (%)	0
9-month follow-up (in-segment)	
Reference lumen diameter, mm	2.85 ± 0.37
Minimal lumen diameter, mm	2.24 ± 0.34
Late lumen loss, mm	0.01 ± 0.34
Diameter stenosis, %	21.28 ± 9.47
Binary stenosis (DS> 50%), n (%)	1 (1.6)

The OCT analysis is described in Table 3. The primary endpoint of mean neointima volume obstruction was 10.5 ± 6.9%. The mean neointima thickness was 110.9 ± 89.8 μm. The proportion of uncovered struts was 2.5%, for malapposed struts 1.1% and for malapposed and uncovered struts 0.7%. Mean incomplete stent apposition area was 0.1 ± 0.1 mm^2. Because OCT was not required per protocol durign index procedure (real practice procedures) observed incomplete appostion can not be categorized as persistent or acquired. Among those stents showing neointimal growth the most common neointimal pattern was the homogeneous (80%). Of note, no subclinical thrombi were observed. An example of a case showing a thin complete intimal coverage is shown in Fig. 4.

Clincal outcomes for the complete cohort of 65 patienst at 12 months follow up is presented in Table 4. No deaths, 1 myocardial infarction (due to a dissection distal to the stent), 2 TLR events (both corresponded to focal restenosis in stent margins) and no stent thrombosis were reported. Among patients undergoing TLR, one coresponded to the single patient showing in-segment binary restenosis in angiographic follow up, and the remaining case was performed nearly 3 months after an angiographic follow up not showing significant restenosis.

4. Discussion

The main findings of this FIM study are; 1) The ihtDEStiny stent shows a very high efficacy in limiting neointimal proliferation as evidenced by a very low neointimal volume obstruction; 2) This high antiproliferative efficacy does not prevent a high degree of struts coverage and appostion at 9 months with complete absence of thrombi.

Current DES show a good efficacy and safety profile derived from aspects of their design that contribute to this overall performance. Among these factors are a thin metallic strut, the antiproliferative drug of the -limus family, and highly biocompatible polymers.

The ihtDEStiny stent has been desgined pooling together the features associated with better performance of current DES in terms of efficacy and safety. This is a very thin cobalt-chromium sirolimus (0.9 μg/mm^2) eluting stent with an oval shape strut with a thickness of 68 μm (Fig. 1). The coating consists in an abluminal dual layer (base + barrier layer) with a biostable fluoropolymer containing a platelet aggregation inhibitor of the salicylate family, the triflusal. Several experiments have

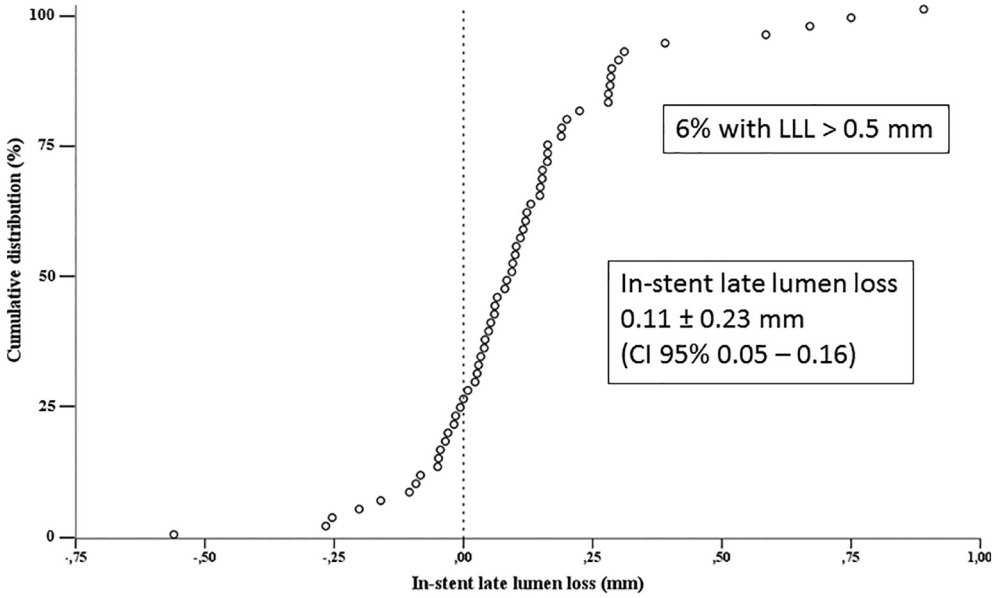

Fig. 3. In-stent late lumen loss distribution at 9 months follow up.

been completed to establish the ability of the polymer to deliver the triflusal and potentially improve the local thromboresistant profile of the device. Those experiments are based on in vitro experiments and currently an in vivo experiment is being developed to establish the triflusal release profile in an intracoronary porcine experiment.

The thin struts allow a more accelerated endothelialization and a lower deposition of platelets and fibrin. The damage that the stent structure exerts on the arterial media would also be attenuated. All this provides a rationale for the observed relationship between a thinner strut and a lower incidence of thrombosis and restenosis [4–6]. The cross-sectional shape of the strut would also have some importance, since an oval profile will facilitate a more laminar flow around it and this would favor a better endothelialization process and less accumulation of thrombotic material around the strut [7]. Regarding the polymer, the fluoropolymers have been shown to be one of the least thrombogenic of all the polymers used in current DES [8–11]. The presence in the coating of an antiplatelet agent triflusal [17], could increase the thromboresistant profile. The coating includes the lateral aspects of the strut, where subclinical thrombi is more commonly detected because of the altered flow conditions [4–7]. The abluminal coating of the stent by the polymer plus the drug has been associated with adequate endothelialization with respect to the conformal coating [13].

Table 3
Optical coherence tomography data at 9 months follow up.

Qualitative lesion-level data:	n=63
Neoitima pattern, n (%):	
Absent	18 (28.6)
Homogeneous	36 (57.1)
Heterogeneous	2 (3.2)
Layered	7 (11.1)
Thrombi	0
Quantitative lesion-level data:	**n=63**
Stent length, mm	20.2 ± 5.5
Reference lumen area, mm^2	7.9 ± 2.3
Lumen area, mm^2	
Minimal	5.5 ± 1.7
Mean	6.9 ± 1.8
Stent area, mm^2	
Minimal	6.5 ± 1.7
Mean	7.7 ± 1.8
Mean ISA area, mm^2	0.1 ± 0.1
Mean neointima area, mm^2	0.8 ± 0.5
Mean neointima volume obstruction, %	10.5 ± 6.9
Area stenosis, %	28.6 ± 15.4
Strut level analysis	**(n=11,326)**
Uncovered struts, n (%)	278 (2.5)
Malapposed struts, n (%)	119 (1.1)
Malapposed and uncovered struts, n (%)	84 (0.7)
Neointima thickness, μm	110.9 ± 89.8

ISA: incomplete stent apposition.

The high resolution of OCT enables characterization of stent healing and vascular responses, as well as accurate quantification of neointimal hyperplasia afterstent implantation. In our study, invasive follow up with OCT was set at 9-months. The reason is that this time point represents a good balance for the assessment of both intimal proliferation and strut coverage/apposition, surrogates of efficacy and safety clinical endpoints respectively. In fact, this is the average time of the studies that evaluate DES with OCT [16].

The procedural device success was 100%, but the rate of periprocedural myocardial infarction (1.5%) could had been underestimated due to the following reasons. First, by application of selection criteria patients with complex lesions were excluded, second, because OCT examination was planned ahead patients showing distal lesions with proximal tortuosity were excluded as well, third, a 74% of patients presented with an acute coronary syndrome, and finally, cardiac enzymes measurement was not systematically performed.

The angiographic analysis yielded a LLL of 0.11 ± 0.23 mm (95% CI 0.05–0.16) and an in-segment binary stenosis of 1.6%, which are among the best reported for the current DES (LLL 0.1–0.3 mm) [18]. Overall, all second and next generation DES show an average LLL of 0.22 (95%CI 0.17–0.26) and the pooled mean LLL in 14 studies evaluating the widely used durable polymer everolimus-eluting stent (EES) was 0.15 mm. The proportion of stents presenting a LLL > 0.5 mm, a parameter related with the risk of TLR, was only of 6%, which is also one of the lowest reported for currently used DES [18].

Regarding the OCT analysis data, the low mean neointima volume obstruction (10.5 ± 6.9%) confirms in a more precise way the angiographic findings. A meta-analysis of studies that included OCT for the evaluation of DES between 6 and 12 months serves as a reference to interpret these findings [16]. The mean neointima thickness of 110.9 ± 89.8 μm is in the range of the most potent DES, such as sirolimus-, biolimus- and everolimus-eluting stents (90–100 μm). The proportion of uncovered struts of 2.5% is very similar to that reported with the EES (2.8%) and the proportion of malapposed struts of 1.1% is also

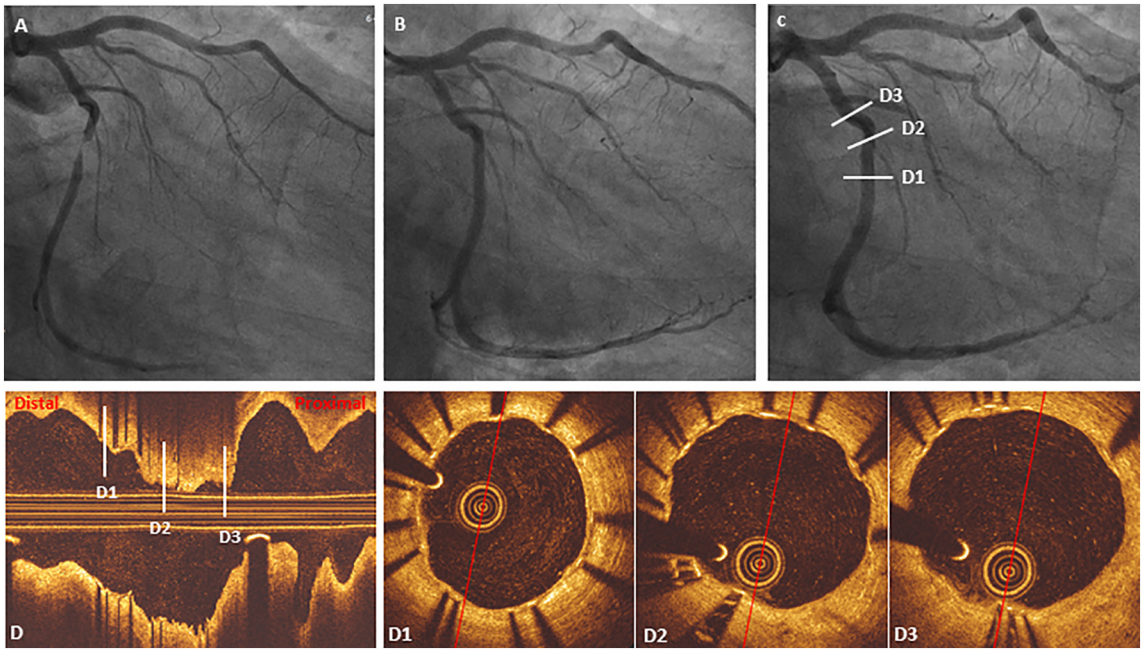

Fig. 4. Angiographic and OCT images corresponding to one of the patients. A) Baseline angiography pre PCI. B) Baseline angiography post PCI. C) 9 months follow-up angiography. D) 9 months follow up OCT.

very comparable to the 0.9% reported for EES. This comparison is more valuable considering that in this pooled analysis the EES were evaluated at 9 months [19,20] and at 12 months [21].

It is noteworthy the absence of subclinical thrombi in this study with ihtDEStiny stent, while in some studies with EES and zotarolimus-eluting stents these were observed in 9–20% of stents [16].

More recently, data from 3 prospective studies including patients with EES implantation and OCT follow-up at 9.0 ± 1.5 months study were merged [22]. In 92 lesions neointimal thickening was 101.7 ± 65.4 μm and neointimal obstruction area was 12.2 ± 7.6%. The rate of uncovered struts was 2.8%.

5. Limitations

This is a single-arm prospective observational study, which is the major limitation. However, the profile of patients and lesions corresponds in general to that of studies with angiographic/OCT follow-up that have served to evaluate other DES. Although the cross-comparison with other studies implies certain limitations, it can help to put these results in context. The multicenter design and the centralization of angiography and OCT analysis add value to the study.

The patients and lesions included in this study were selected under a set of inclusion and exclusion criteria, so the results are applicable to the type of patients and lesions included.

No systematic OCT evaluation was performed during the PCI procedure. Certainly this would have made it possible to define the acquired or persistent character of incomplete appositions, but we considered that the implantation procedure of the stents should be as close as possible to that corresponding to real practice. Ultimately, the objective of the study was to evaluate the performance of the stent under the most common implantation conditions. In fact, the use of intravascular imaging was 10.7%, which is the average in clinical practice in our setting [23].

The 9-month evaluation may not detect the maximum degree of neointimal proliferation, and it cannot be considered so early as to evaluate intinal coverage in the short term. However, 9 months is an optimal time point to estimate both the intimal proliferation response and the intimal coverage in the medium term, being this the average follow-up time in the studies that examine DES with OCT [16,22].

Table 4
Clinical follow up at 12 months.

	N=65
Death	0
Target vessel myocardial infarction	1 (1.5%)
Target lesion revascularization	2 (3%)
Stent thrombosis (definite or probable)	0
Major bleeding	0
Stroke	0

6. Conclusions

The ihtDEStiny stent has been desgined with the most advanced technical features aimed to enhance efficacy and safety. At 9 months follow up examination with OCT, this stent shows a very low degree of intimal proliferation (surrogate for efficacy) while showing a very low rate of uncovered/malapposed struts and no subclinical thrombi at all (surrogate for safety).

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Study design, selection of participating centers, collection, management, and interpretation of data, and manuscript preparation were exclusive responsibilities of the investigators with no involvement/interference of the funding company.

Declaration of competing interest

Jose M. de la Torre Hernández

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This work has not been published previously and it is not under consideration for publication elsewhere.

The manuscript has been approved by all authors and tacitly or explicitly by the responsible authorities where the work was carried out, and if accepted, it will not be published elsewhere in the same form, in English or in any other language, including electronically without the written consent of the copyright-holder.

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