Supplemental Materials

Supplemental Files are intended for review purposes, and are intended for publication as an online data supplement.

The 16 Participating Sites in China:
Locations

China, Hunan

The Third Xiangya Hospital of Central South University
Changsha, Hunan, **China**

China, Inner Mongolia

The First Affiliated Hospital of Baotou University
Baotou, Inner Mongolia, **China**

Inner Mongolia People'S Hospital
Hohhot, Inner Mongolia, **China**

The First Affiliated Hospital of Inner Mongolia Medical University
Hohhot, Inner Mongolia, **China**

China, Jiangxi

The Second Affiliated Hospital of Nanchang University
Nanchang, Jiangxi, **China**

China, Shaanxi

The First Affiliated Hospital of Xi'An Jiaotong University
Xi'an, Shaanxi, **China**

China, Zhejiang

Sir Run Run Shaw Hospital School of Medicine, Zhejiang University
Hangzhou, Zhejiang, **China**

China

The General Hospital of Shenyang Military Region
Area Of Shenyang, **China**

Fu Wai Hospital, National Center for Cardiovascular Disease
Beijing, **China**

The First Hospital of Jilin University
Changchun, **China**

The Second Xiangya Hospital of Central South University
Changsha, **China**

The First Hospital of Lanzhou University
Lanzhou, **China**

Shanghai Ninth People's Hospital
Shanghai, **China**

West China Hospital, Sichuan University
Sichuan, **China**

The Second Hospital of Shanxi Medical University
Taiyuan, **China**

TEDA International Cardiovascular Hospital
Tianjin, **China**

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Inclusion Criteria:

- Stable and unstable angina pectoris (AP), old myocardial infarction (OMI), or confirmed evidence of myocardial ischemia;
- Primary in situ coronary artery lesions (up to two target lesions and up to 2 stents per lesion);
- Visual target lesion length ≤40mm;
- Visual reference vessel diameter of 2.5-3.5mm;
- Visual diameter stenosis ≥70%;
- Patients with indications for coronary artery bypass surgery (CABG);
- Subjects participate voluntarily and signed an informed consent willing to accept angiographic and clinical follow-up.

Exclusion Criteria:

- Acute myocardial infarction (AMI) occurred within 7 days prior to the procedure; post-MI complicated with elevated levels of cardiac enzymes (CK-MB, cTNT / I);
- CTO (TIMI-0) lesions, left main lesions, ostial lesions, bypass graft lesions, bifurcation lesions (lateral side branch reference vessel diameter≥2.5mm), restenosis in-stent and three-vessel disease that need to be treated;
- Severe calcified lesions for which balloon pre-dilation is expected to be unsuccessful;
- Tortuous lesions that render stent crossing difficult;
- NYHA class ≥ III or left ventricular ejection fraction <40%;
- Implantation of other stents in the past year;
- Pregnant or breast-feeding patients or patients planning to get pregnant within the following year;
- Subjects with bleeding tendency or coagulation disorder or PCI contraindications and / or anticoagulant therapy contraindications or who have not tolerated dual antiplatelet treatment within a year to date;
- Presence of other diseases (such as cancer, malignancies, congestive heart failure, organ transplantation or candidate for it) or history of substance abuse (alcohol, cocaine, heroin, etc.), poor protocol compliance or life expectancy of less than 1 year;
- Allergic to one of following: aspirin, heparin, clopidogrel, sirolimus (rapamycin), PLGA polymers, contrast agents and metal;
- Severe liver and kidney dysfunction (ALT or AST level 3 times greater than the upper limit of normal; eGFR <30ml/min);

- Patients participating in any other clinical trial and who have not completed follow-up to the primary endpoint;
- Study subjects with poor compliance judged by investigators, with poor possibility to complete study in accordance with requirements.

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CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	4
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	7
	2b	Specific objectives or hypotheses	8
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	8-9
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	none
Participants	4a	Eligibility criteria for participants	8-9
	4b	Settings and locations where the data were collected	8
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	9
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	11
	6b	Any changes to trial outcomes after the trial commenced, with reasons	none
Sample size	7a	How sample size was determined	12
	7b	When applicable, explanation of any interim analyses and stopping guidelines	none
Randomisation:			

Sequence generation	8a	Method used to generate the random allocation sequence	9
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	9
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	9
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	9
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	8
	11b	If relevant, description of the similarity of interventions	9
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	13
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	13
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	9
	13b	For each group, losses and exclusions after randomisation, together with reasons	9,12-13
Recruitment	14a	Dates defining the periods of recruitment and follow-up	8,11
	14b	Why the trial ended or was stopped	none
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	26-27
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	12-13
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	14-15
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	14-15

Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	14-15
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	14-15
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	19-20
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	16-20
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	16-20
Other information			
Registration	23	Registration number and name of trial registry	8
Protocol	24	Where the full trial protocol can be accessed, if available	5
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	20

- *We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

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Type specifications of MiStent and TIVOLI

Experimental Device: Mistent SES® system

Length (mm)	Diameter (mm)	Diameter (mm)	Diameter (mm)	Diameter (mm)
9	2.5	2.75	3.0	3.5
13	2.5	2.75	3.0	3.5
15	2.5	2.75	3.0	3.5
19	2.5	2.75	3.0	3.5
23	2.5	2.75	3.0	3.5
27	—	2.75	3.0	3.5
30	—	2.75	3.0	3.5

Manufacturer: Micell Technologies Ireland Limited, ~~,~~Durham, North Carolina, USA.

Control Device: TIVOLI stent

Length (mm)	Diameter (mm)	Diameter (mm)	Diameter (mm)	Diameter (mm)
10	2.5	2.75	3.0	3.5
15	2.5	2.75	3.0	3.5
18	2.5	2.75	3.0	3.5
21	2.5	2.75	3.0	3.5
25	2.5	2.75	3.0	3.5
30	2.5	2.75	3.0	3.5

Manufacturer: EssenTech, Beijing, China.

Specifications of MiStent BP-SES Versus TIVOLI BP-SES.

Variables	MiStent	TIVOLI
Platform material	Cobalt-chromium (L605)	Cobalt-chromium (L605)
Strut thickness (μm)	64	80
Diameter (mm)	2.50, 2.75, 3.00, 3.50	2.50, 2.75, 3.00, 3.50
Length (mm)	9, 13, 15, 19, 23, 27, 30	10, 15, 18, 21, 25, 30
Drug	Crystalline Sirolimus	Sirolimus
Drug release	Up to 270 days	75% at 28 days
Polymer	PLGA (biodegradable)	PLGA (biodegradable)
Polymer thickness (μm)	5 on the luminal surface 15 on the abluminal surface	5.5

BP-SES: Biodegradable polymer sirolimus eluting stent; PGLA: Polylactic-co-glycolic acid.

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Endpoints

Primary efficacy endpoint:

- A non-inferiority comparison at 9 months after index procedure of in-stent late lumen loss (LLL) in the MiStent group compared with the TIVOLI group. In our study, LLL was defined as the difference in millimeters between the diameter of a stented segment post-procedure compared with the follow-up angiogram at 9 months.

Secondary endpoints:

- Success rate of stent implantation (including device success, lesion success and clinical success);
- Binary restenosis rates (defined as ≥50% diameter stenosis) in-stent, at proximal or distal edge of the stent, and in-segment;
- In-segment LLL and percentage of diameter stenosis (defined as difference between reference vessel diameter and minimal lumen diameter/reference diameter×100) in-segment;
- Device-related clinical cardiovascular composite endpoint, defined as target lesion failure (TLF), including cardiac death, target vessel myocardial infarction and clinically driven target lesion revascularization;
- Patient oriented composite endpoint (PoCE), including all-cause death (cardiac and non-cardiac), nonfatal myocardial infarction, any revascularization or stroke;
- Incidence of stent thrombosis (ST) (definite, probable, possible stent thrombosis at early, late and very late periods) according to the definition of the Academic Research Consortium (ARC).