AsiaIntervention 2017;3:111-120

Defining optimal stent overexpansion strategies for left main stenting: insights from bench testing

Jiang Ming Fam[1,2]*, MBBS; Peter Mortier[3,4], PhD; Matthieu De Beule[3,4], MS, PhD; Tim Dezutter[3,4], MS; Nicolas Van Mieghem[1], MD, PhD; Roberto Diletti[1], MD, PhD; Bert Everaert[1,5], MD, PhD; Soo Teik Lim[2], MBBS; Felix Zijlstra[1], MD, PhD; Robert-Jan van Geuns[1], MD, PhD

1. Thoraxcenter, Erasmus University Medical Center, Rotterdam, the Netherlands; 2. National Heart Centre Singapore, Singapore; 3. IBiTech-bioMMeda, iMinds Medical IT, Ghent University, Ghent, Belgium; 4. FEops, Ghent, Belgium; 5. AZ Monica Hospital, Antwerp, Belgium

This paper also includes supplementary data published online at: www.asiaintervention.org

KEYWORDS

- bifurcation
- drug-eluting stent
- left main

Abstract

Aims: Left main stenting frequently requires overexpansion of stents which can be performed by proximal optimisation technique (POT) or final kissing balloon dilation (FKBD). Yet, there are limited data concerning the effect of post-dilation of metallic stents beyond the overexpansion limit. The objectives of this study were to evaluate stent performance after overexpansion using POT or FKBD.

Methods and results: We deployed 4.00 mm drug-eluting platinum-chromium stents in silicone models of 6.00 mm diameter. We compared stent expansion and apposition using: 1) POT with 6.00 mm balloons using low, standard and high pressures (LP, SP and HP, respectively), and 2) final kissing balloon dilation (FKBD) using undersized (US) balloons at SP and optimally sized (OS) balloons at LP and SP. The platinum-chromium 4.00 mm stent can be expanded to an outer diameter of 5.10 mm by POT using a 6.00 mm balloon at LP. Further post-dilatation at higher pressures (SP, HP) resulted in an outer diameter of 6.00 mm. FKBD with US balloons resulted in a high ellipticity index and malapposition; with OS balloons, stent area improved but ellipticity and malapposition were still higher compared to POT. After overexpansion, the radial strength of metallic stents was maintained.

Conclusions: In PCI involving relatively larger vessel diameters such as left main stenting, POT but not FKBD can safely expand the platinum-chromium 4.00 mm stent beyond the overexpansion limit to 6.00 mm with optimal stent apposition and performance. POT may be the technique of first choice to achieve optimal stent expansion in left main stenting but requires higher pressures.

**Corresponding author: Department of Cardiology, National Heart Centre Singapore, 5 Hospital Drive, Singapore 169609, Singapore. E-mail: fam.jiang.ming@singhealth.com.sg*

SUBMITTED ON 28/08/2016 - REVISION RECEIVED ON 1st 06/12/2016 / 2nd 29/12/2016 / 3rd 06/05/2017 - ACCEPTED ON 28/06/2017

DOI: 10.4244/AIJ-D-16-00012

Abbreviations

DES	drug-eluting stent
EI	ellipticity index
FKBD	final kissing balloon dilation
FKBD-US	final kissing balloon dilation undersized
FKBD-OS/LP	final kissing balloon dilation - optimally sized low pressure
FKBD-OS-SP	final kissing balloon dilation - optimally sized standard pressure
ID	inner diameter
MA	malapposition area
NC	non-compliant
OD	outer diameter
PCI	percutaneous coronary intervention
POT	proximal optimisation technique
POT-LP	proximal optimisation technique low pressure
POT-SP	proximal optimisation technique standard pressure
SAR	surface to artery ratio
SC	semi-compliant

Introduction

With improved percutaneous coronary intervention (PCI) techniques, PCI has emerged as a safe option for revascularisation in selected patients with unprotected left main coronary artery disease with good long-term outcomes[1,2]. However, left main PCI has remained a technically challenging procedure with several key considerations. The left coronary artery is of larger diameter, frequently above 5 mm. In an intravascular ultrasound (IVUS) study on the use of drug-eluting stents (DES) in left main PCI, the maximal diameter of the distal left main was 5.7±0.7 mm on average[3]. Left main stenting often involves bifurcation treatment and deployment of a single stent across vessels with marked disparity in diameters[4]. Thus, key procedural challenges to achieve adequate stent expansion while maintaining minimal malapposition still remain.

In left main stenting using current metallic stents, overexpansion using either proximal optimisation technique (POT) or final kissing balloon dilation (FKBD) is widely performed to minimise stent malapposition. The phenomenon of malapposition is of particular importance for two reasons: one is the acute risk during the procedure where subsequent vessel rewiring and balloon dilatations might engage the malapposed space immediately deforming stent integrity, and the second, in the longer term, is increasing the risk of stent thrombosis[5-7]. For bifurcation lesions, FKBD has traditionally been the method to reach maximal expansion[8,9]. However, clinically, this is limited by side branch diameters and will result in undesired elliptical deformation. POT is another commonly used bifurcation technique that was devised later by Darremont[10] to achieve overexpansion at the carina using short, larger balloons. Although earlier studies have been performed to evaluate the results of stent oversizing and the impact of post-dilation on strut geometry in bench testing situations[9,11-14], there is still a paucity of data concerning the feasibility of aggressive post-dilation of metallic stent platforms within large left main coronary phantoms performed by either FKBD or POT to achieve adequate expansion with optimal apposition[3] and concerning the impact on mechanical stent performance such as radial strength[4]. The objectives of this study were to compare expansion and apposition of stents overexpanded by POT and FKBD from the nominal diameter of 4.00 mm beyond the recommended expansion limit to 6.00 mm in a bench testing scenario and to investigate the mechanical stent performance of overexpanded stents.

Methods

In vivo bench testing of thin-strut (81 µm) platinum-chromium DES (SYNERGY™ II; Boston Scientific, Marlborough, MA, USA) was conducted. All experiments were performed in the Boston Scientific Research and Development Facility at Maple Grove, MN, USA, between July and September 2014. **Table 1** shows the models we used in our bench testing. In brief, we performed the following bench tests using the SYNERGY II drug-eluting stent (DES) in silicone phantom models with a diameter of 6.00 mm:

– To measure the effect of overexpansion on the stent performance of a 4.00 mm SYNERGY stent with 6.00 mm balloons

Table 1. Summary of post-dilation methods performed for the stent proximal ends.

			Stent deployment			First post-dilation			Second post-dilation		
Post-dilation method	Group number	Sample size	Stent	Size (mm)	Deployment pressure (atm)	Post-deployment balloon	Size (mm)	Pressure (atm)	Post-deployment balloon	Size (mm)	Pressure (atm)
POT-SC/LP	1	3	SYNERGY	4.0×28	16	Apex	5.0×15	9	Maverick XL	6.0×15	6
POT-SC/SP	2	10	SYNERGY	4.0×28	16	Apex	5.0×15	12	Maverick XL	6.0×15	14
POT-NC/HP	3	3	SYNERGY	4.0×28	16	NC Quantum	5.0×15	16	NC Emerge	6.0×15	24
FKBD-US/SP	4	3	SYNERGY	4.0×28	16	Apex	5.0×15	12	Apex	3.5×15+ 4.0×15	12
FKBD-OS/LP	5	3	SYNERGY	4.0×28	16	Apex	5.0×15	12	Apex	4.0×15+ 5.0×15	4
FKBD-OS/SP	6	3	SYNERGY	4.0×28	16	Apex	5.0×15	12	Apex	4.0×15+ 5.0×15	12

FKBD: final kissing balloon dilation; HP: high pressure; LP: low pressure; NC: non-compliant; OS: optimally sized; POT: proximal optimisation technique; SC: semi-compliant; SP: standard pressure; US: undersized

(semi-compliant [SC] Maverick™ XL or non-compliant [NC] Emerge™; both Boston Scientific) using:
  - POT at low pressure (LP) of 6 atm (Group 1 POT-SC/LP),
  - POT at standard pressure (SP) of 14 atm (Group 2 POT-SC/SP),
  - POT at high pressure (HP) of 24 atm (Group 3 POT-NC/HP).
- To evaluate the effect of common clinical FKBD methods using:
  - The relatively undersized (US), but commonly used, 3.50 mm and 4.00 mm (Apex™; Boston Scientific) balloons at standard pressure (SP) of 12 atm (Group 4 FKBD-US/SP)
  - The optimally (according to Finet's law) sized (OS) 4.00 mm and 5.00 mm (Apex) balloons at LP of 4 atm (Group 5 FKBD-OS/LP) and at SP of 12 atm (Group 6 FKBD-OS/SP).
- To evaluate the effect of overexpansion on mechanical stent performance by overexpanding the stent beyond the overexpansion limit to 6.00 mm.

The 3.5 and 4.0 mm balloons were used for FKBD as this was the largest combination for kissing balloons used in the clinical setting of our hospital. The inflation pressures needed for full overexpansion of the balloons to the intended diameters were chosen.

Comparison of stent expansion and malapposition among the six models was achieved by measuring the dimensions and mechanical characteristics of the stents after overexpansion **(Table 1)**. Detailed information regarding the methodology is provided in the **Supplementary Appendix**. The malapposition area (MA/mm^2) of each stent was the difference of tube inner diameter (ID) area and stent outer diameter (OD) area. The ellipticity index (EI) is the ratio of maximum stent ID to minimum stent ID. The mechanical performance of the stents was evaluated at various sizes from 4.00 mm (baseline) to 6.00 mm (overexpansion as measured by average maximum compression resistance [hoop force/length: N/mm]). Mechanical characteristics evaluated included radial strength, stent length, elastic recoil and percentage surface to artery ratio (SAR). Forty stents (10 stents per group, at 4.00 mm, 5.00 mm, 5.75 mm and 6.00 mm) were used to collect the radial strength data since this is a destructive test. Stent length was also captured from these stents as it is an input factor in the radial strength calculation (force/length). The average length values from these groups were also used to calculate vessel area at each diameter in the SAR calculation. The recoil was measured sequentially from the same 10 stents deployed to 4 mm, then post-dilated to 5 mm, 5.75 mm and 6.00 mm.

STATISTICAL ANALYSIS

Descriptive statistical analysis was performed with continuous variables expressed as averages (standard deviation) and with categorical variables presented as counts (percentage). The ANOVA test was used for comparison between groups. All statistical tests were carried out at the 5% level of significance in SPSS, Version 21 (IBM Corp., Armonk, NY, USA).

Results

STENT OUTER DIAMETER AND STENT OUTER AREA

A total of 25 stents were subject to bench testing in the following models: POT-SC/LP (n=3), POT-SC/SP (n=10), POT-NC/HP (n=3), FKBD-US/SP (n=3), FKBD-OS/LP (n=3) and FKBD-OS/SP (n=3). Representative phantoms of the respective models post dilation are shown in **Figure 1**. Detailed results of the stent measurements in the various models are tabulated in **Table 2**. Additional data regarding stent measurements are shown in **Supplementary Table 1** in the **Supplementary Appendix**. Using the POT-SC/LP model, the 4.00 mm stent reached a maximum stent outer diameter of 5.10 mm using a 6.00 mm SC balloon at 6 atm. In POT-SC/SP and POT-NC/HP, further post-dilatation with higher pressures of 14 atm and 24 atm, respectively, resulted in the maximum stent outer diameter reaching 6.00 mm and 6.22 mm, respectively, with a stent outer area of 30.30 mm^2 and 28.60 mm^2 as the final result. These were the only models in which the stent outer area reached the target stent outer area of 28.30 mm^2 (based on a stent outer diameter of 6.00 mm). The POT-SC/SP model was repeated 10 times without any fractures on visual inspection, demonstrating a safety margin above the designated expansion limit, and with minimal malapposition in a 6.00 mm vessel. We achieved the highest stent outer diameters

Table 2. Actual stent measurements after overexpansion.

Group number	Post-dilation method	Sample size	Stent ID				Stent OD			Tube ID max			
			Stent ID max (mm)	Stent ID min (mm)	EI_{ID}	Stent ID area (mm^2)	Stent OD max (mm)	Stent OD min (mm)	Stent OD area (mm^2)	Tube ID max (mm)	Tube ID min (mm)	Tube ID area (mm^2)	Malapposed area (ID_{Tube}-OD_{Stent}) (mm^2)
1	POT-SC/LP	3	5.00	5.00	1.0	19.60	5.10	5.10	20.80	6.40	5.90	29.20	8.40
2	POT-SC/SP	10	5.90	5.90	1.0	27.20	6.00	6.00	28.60	6.20	6.20	29.70	1.10
3	POT-NC/HP	3	6.07	6.07	1.0	28.77	6.22	6.22	30.30	6.22	6.22	30.30	0
4	FKBD-US/SP	3	6.30	4.10	1.5	21.40	6.50	4.30	22.80	6.70	5.60	29.00	6.20
5	FKBD-OS/LP	3	5.50	4.60	1.2	19.70	5.70	4.80	20.90	6.50	5.80	29.10	8.20
6	FKBD-OS/SP	3	6.70	4.70	1.4	25.70	6.90	4.90	27.20	6.90	5.30	29.00	1.80

EI: ellipticity index; FKBD: final kissing balloon dilation; ID: inner diameter; HP: high pressure; LP: low pressure; NC: non-compliant; OD: outer diameter; OS: optimally sized; POT: proximal optimisation technique; SC: semi-compliant; SP: standard pressure; US: undersized

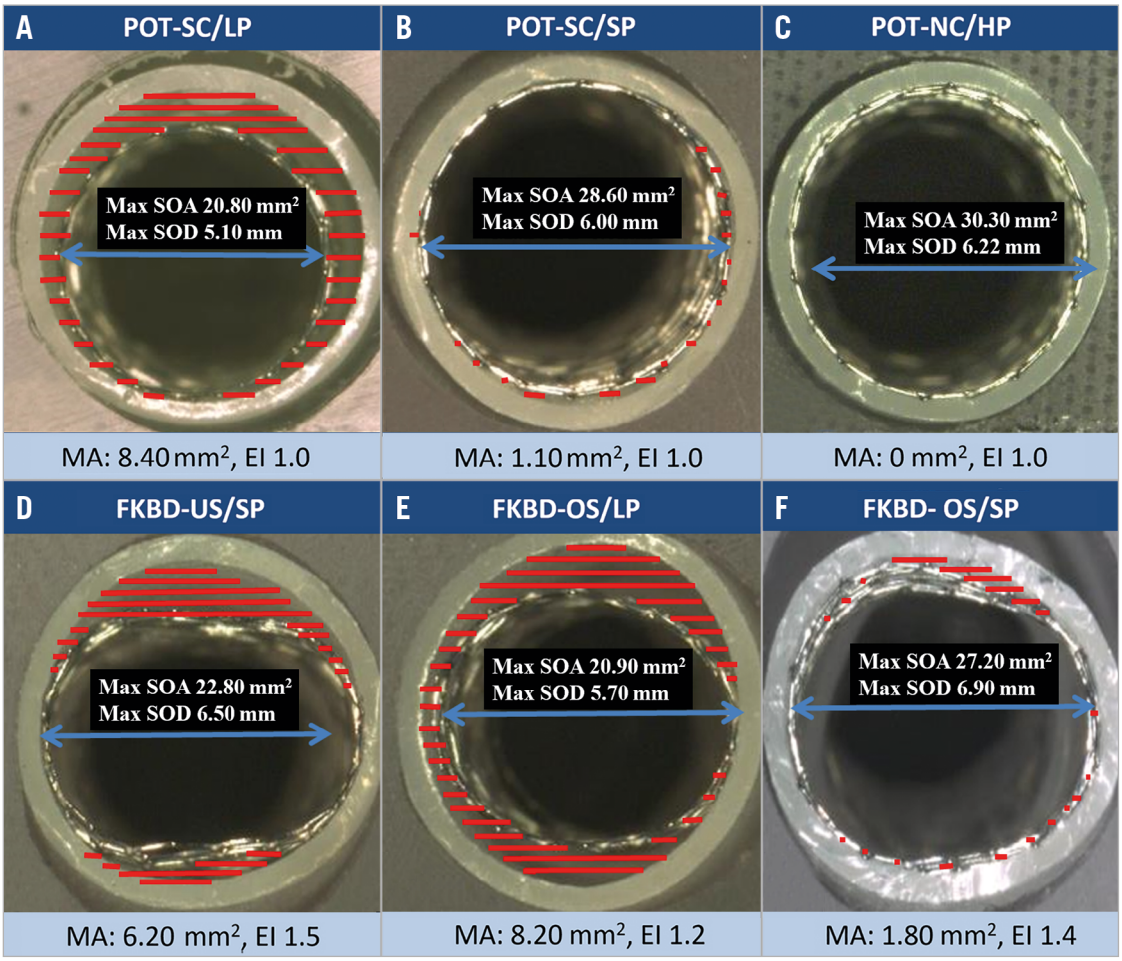

Figure 1. *Cross-sections of stents (proximal edge) post dilation in bench testing. A) & B) Cross-sections of the proximal edge of the stents after post-dilation by POT using 6.00 mm balloons (semi-compliant [SC] Maverick XL) at low pressure (LP) of 6 atm (POT-SC/LP) and standard pressure (SP) of 14 atm (POT-SC/SP), respectively. Optimal ellipticity index (EI) was seen in the POT models. C) The SYNERGY stent was post-dilated to 6 mm using the new NC Emerge 6 mm balloon at very high pressures of 24 atm (POT-NC/HP). D) - F) Cross-sections of the proximal edge of the stents after post-dilation by FKBD using Apex balloons: i) the relatively undersized (US), but commonly used, 3.50 mm and 4.00 mm balloons at standard pressure (SP) of 12 atm (Panel D - FKBD-US/SP), ii) optimally sized (OS) 4.00 mm and 5.00 mm balloons at LP of 4 atm (Panel E - FKBD-OS/LP), and iii) at SP of 12 atm (Panel F - FKBD-OS/SP), correspondingly. FKBD resulted in an elliptical shape of the proximal edge of the stents. Higher pressures will result in larger diameters and stent areas but also in increased ovalisation and malapposition. FKBD: final kissing balloon dilation; LP: low pressure; MA: malapposed area; POT: proximal optimisation technique; RBP: rated burst pressure; SOD: stent outer diameter; US: undersized*

of 6.90 mm in the FKBD-OS/SP model. However, the stent outer area of 27.20 mm² in FKBD-OS/SP was still significantly lower compared to that of POT-SC/SP and POT-NC/HP. **Figure 2A** and **Figure 2B** show the significant differences in the stent outer diameters and stent outer areas following expansion among the six models. We further investigated the relation of stent diameters to pressures as they are gradually overexpanded by 6.00 mm balloons, showing that the largest outer stent diameter is possible with an NC balloon **(Figure 3)**.

ELLIPTICITY INDEX (EI)

Among the five models, we found that POT-SC/SP and POT-NC/HP resulted in the most optimal EI. With POT, the EI was 1.0 whereas all FKBD models resulted in elliptical stents (with the EI ranging from 1.2 to 1.5) with significant potential for malapposition, in particular with the use of US balloons. Under the FKBD-US/SP model where balloon diameters are frequently used in the clinical setting, the 3.50 mm and 4.00 mm balloons resulted in the highest EI of 1.5. **Figure 2C** shows the significant differences in EI among the different models.

MALAPPOSED AREA (MA)

Among the five models, the POT-NC/HP resulted in the least amount of MA **(Table 2, Figure 2D)**. Of note, among the POT models, the POT-LP model also exhibited a high MA (8.40 mm²) which only improved with higher pressures employed in the

POT-SC/SP or NC/HP models. Importantly, with FKBD, MA was higher in the FKBD- US/SP, OS/LP and OS/SP models (MA was 6.20, 8.20 and 1.80 mm^2, respectively).

STENT MECHANICAL PERFORMANCE AT OVEREXPANSION LIMITS

Figure 4 shows the impact of overexpansion on stent mechanical performance. Additional data regarding stent performance measurements are shown in **Supplementary Table 2** in the **Supplementary Appendix**. The radial strength of the stent was similar among the control, 5.00 mm and 5.75 mm groups; however, it significantly increased at 6.00 mm diameter (0.26±0.01; 0.27±0.02; 0.28±0.04; 0.38±0.04 N/mm, respectively, p<0.001). Stent recoil significantly decreased from 2.9% to 1.4% at larger sized diameters (p<0.01). There was a significant change in measured average stent length from 16.1±0.2 mm at 4.0 mm to 17.5±0.5 mm and 16.8±0.6 mm at 5.0 and 5.75 mm, respectively (p<0.01). Percentage stent surface to artery ratio calculated on the manufacturer-provided data decreased from 14.2% at 4.0 mm to 9.4% at 6.00 mm **(Supplementary Table 3)**.

Discussion

In this study, we investigated whether a 4.00 mm SYNERGY stent could be overexpanded beyond the recommended expansion limit to 6.00 mm. We subsequently compared different expansion techniques to achieve optimal stent apposition in a 6.00 mm phantom model. In addition, we evaluated the impact of overexpansion on the mechanical characteristics of the stent.

The main findings were that:

– The 4.00 mm thin-strut platinum-chromium stent can be expanded to a 6.00 mm outer stent diameter using high-pressure SC and NC coronary balloons. Of note, if low pressures were used, a maximal stent diameter of only 5.10 mm could be obtained using correctly sized balloons in the POT-SC/LP model.
– POT-SC/SP and POT-NC/HP resulted in more optimal EI and minimal MA while achieving adequate overexpansion compared to FKBD.
– FKBD also requires high-pressure inflation to achieve significant overexpansion, resulting in stent eccentricity and focal malapposition.
– Radial strength was still maintained despite stent overexpansion. Stent recoil and % surface to artery ratio decreased as stents were overexpanded.

Studies have shown that clinical outcomes after PCI are linked to the ability of metallic stents to reach adequate stent expansion and maintain elastic recoil, without compromising on radial strength, thereby achieving a large final lumen. Incomplete stent expansion is considered a predictor of stent thrombosis, and high-pressure post-dilation has generally been recommended to avoid incomplete stent apposition and to reduce the risk of adverse outcomes[16]. A consensus statement from the European Bifurcation Club recommended the use of POT to restore stent geometry and

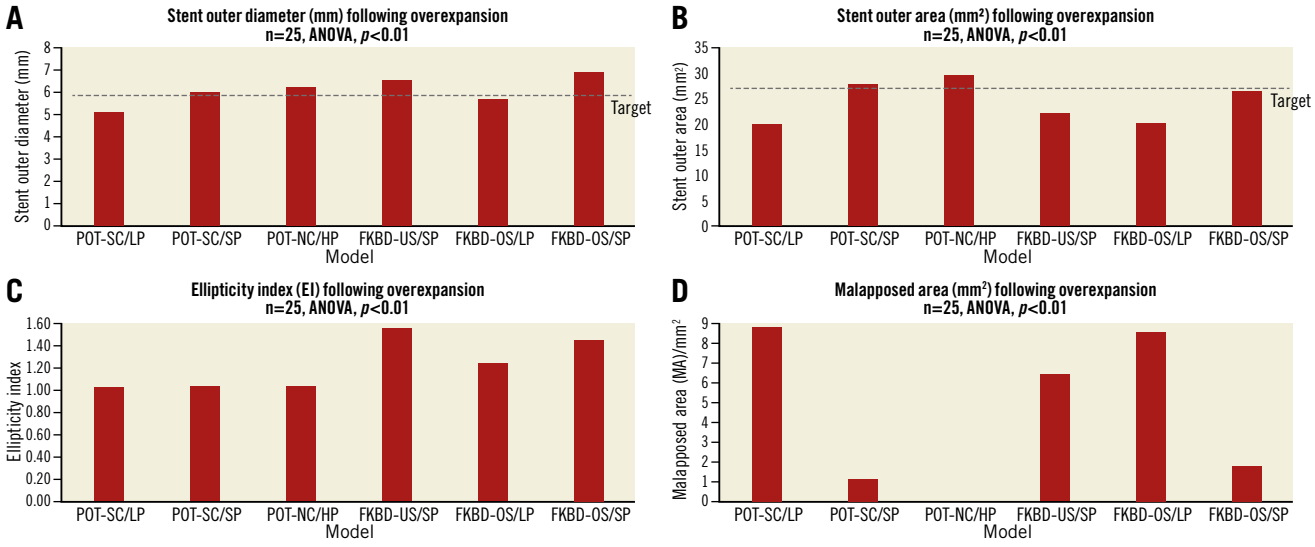

Figure 2. *Comparison of stent measurements among the models. A) Stent outer diameter (mm) following overexpansion. Stent outer diameter could reach a target of 6.0 mm in three of the six models as shown. B) Stent outer area (mm^2) following overexpansion. The stent outer area could reach the target of 28.3 mm^2 in only the POT-SC/SP and NC/HP models. The target area is based on a 6.0 mm circular stent diameter. C) Ellipticity index following overexpansion. An ideal ellipticity index of 1.0 was achieved in the POT models but not in the FKBD models. D) Malapposed area (mm^2) following overexpansion. Among the models tested, POT-NC/HP resulted in the least amount of MA. The POT-SC/LP model also exhibited a high MA (8.40 mm^2) which only improved with higher pressures employed in the POT-SC/SP and POT-NC/HP models. FKBD: final kissing balloon dilation; HP: high pressure; LP: low pressure; NC: non-compliant; OS: optimally sized; POT: proximal optimisation technique; SC: semi-compliant; SP: standard pressure; US: undersized*

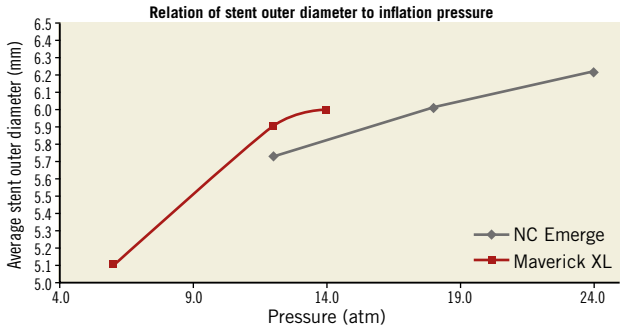

Figure 3. *The relation of the change in stent diameters to pressure used for stent expansion using 6.00 mm balloons (SC Maverick and NC Emerge). Very high pressures were required to overexpand the stents at 5.5 to 6.0 mm diameters. The preserved radial strength of the SYNERGY allows it to be post-dilated with a 6 mm balloon to RBP without fractures. Note: Maverick XL RBP=14 atm; NC Emerge RBP=18 atm.*

minimise malapposition in large vessels and proximal to the carina in bifurcation lesions[10]. It is especially useful in the presence of large side branches as it allows the operator to match the proximal segment of the main branch stent with the main branch diameter by means of a short balloon adapted to the proximal segment. This study added information on the high pressures needed to reach maximum overexpansion typically necessary in left main PCI. However, such adequately sized balloons may not always be available and FKBD is still frequently the final step in left main PCI.

Numerous studies have documented that more complete stent expansion is associated with a reduction in late restenosis[17]. The MUSIC trial showed how the use of intravascular ultrasound (IVUS) criteria (such as the EI) may improve acute and six-month clinical and angiographic outcomes[18]. In a study by Kang et al[19], the minimal stent area was an important factor in predicting angiographic restenosis. This was found to be 5.0 mm^2 for the left circumflex artery ostium, 6.3 mm^2 for the left anterior descending artery ostium, 7.2 mm^2 for the polygon of confluence, and 8.2 mm^2 for the proximal left main above the polygon of confluence.

The recommended stent overexpansion is generally between 0.5 mm and 0.75 mm above the largest nominal diameter. Previous studies have reported results of DES overexpansion experiments in bench testing[20] and with the use of computer modelling[21]. In an earlier study by Basalus et al, bench testing on the impact of large partial post-dilation for overexpanded DES on micro-CT assessment showed differences in strut dimensions which varied in relation to position and type of stent platform tested[11]. However, to the best of

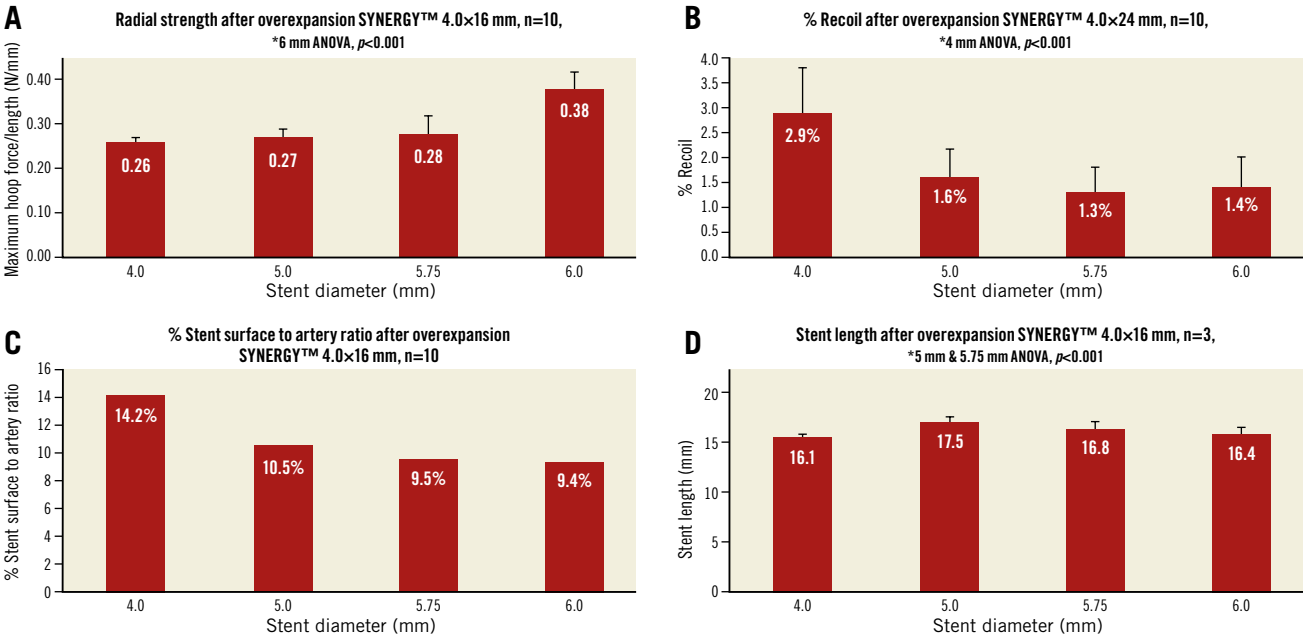

Figure 4. *Impact of overexpansion on stent mechanical performance. A) Radial strength is still maintained even at the overexpansion limit. Radial strength was not affected in overexpanded stents. There were no significant differences in the radial strength; it actually showed an increasing trend as measured by average maximum compression resistance (hoop force/length: N/mm) among the 4.00 mm, 5.00 mm, 5.75 mm and 6.00 mm groups (p=0.20). B) Stent recoil shows a decreasing trend when the stent reaches the overexpansion limit. Stent recoil was significantly decreased as the stent size increased (p<0.01). C) Percentage surface to artery ratio change in relation to stent diameter. Percentage stent surface to artery ratio (calculated as a ratio of stent outer surface area and outer vessel area multiplied by 100) decreases as the diameter of the stent increases from 4.00 mm to 6.00 mm. D) Stent length changes as the stent approaches the overexpansion limit. There was a significant change in measured average stent length when the stents were expanded from a diameter of 4.00 mm to 6.00 mm (p<0.01). Detailed measurements are provided in online Supplementary Table 2.*

our knowledge, neither has a comparison of the different post-dilation strategies such as POT and kissing balloon dilation been carried out nor has the mechanical response of overexpanded stents been evaluated. In our bench test model, the FKBD technique resulted in more elliptical stent geometry with higher malapposition compared with POT, regardless of the size of balloon or pressures used.

In a clinical study conducted by Shand et al[3], the use of DES in left main stenting was evaluated with IVUS. The BioMatrix Flex™ (Biosensors, Bülach, Switzerland) (3.5 and 4.0 mm stents), PROMUS Element™ (Boston Scientific) (3.5 and 4.0 mm stents) as well as the Resolute Integrity® (Medtronic, Minneapolis, MN, USA) (3.5 mm stent) were implanted followed by post-dilation with 5.5 or 6.0 mm balloons. In a subgroup of 31 patients who had undergone left main PCI with post-stent IVUS images available for analysis, the mean maximal stent area (at the proximal left main) and mean maximal stent diameter achieved were 19.7±3.7 mm^2 and 5.5 (4.7-6.4) mm for the BioMatrix Flex 4.0 mm stent and 20.6±2.8 mm^2 and 5.3 (4.3-6.3) mm for the PROMUS Element 4.0 mm stent. The results appear comparable with the stent measurements achieved in our study. Our study showed that overexpansion of a 4.0 mm metallic stent platform can be achieved beyond the recommended overexpansion limit with minimal malapposition and optimal ellipticity, which holds potential for favourable clinical outcomes. We believe that our study set-up represented a frequent clinical situation where the diameter of the left main artery is larger than that of clinically available (and approved) stents. Most coronary stents are only available up to 4 mm, whereas previous IVUS studies[3] showed that the diameter of most left main arteries ranges from 5-6 mm in diameter. For these vessels, the risk of coronary artery rupture will be minimal. The use of IVUS in left main stenting as recommended in European guidelines[1] will also confer additional safety against adverse procedural outcomes such as coronary artery rupture by providing additional information about the vessel dimensions. This, however, should be further studied in clinical trials using intravascular imaging. This would be particularly relevant if we were to evaluate the suitability of current-generation DES for the treatment of left main stenosis in which vessel diameters routinely extend beyond 5.00 mm.

In the present study, stent diameters were measured directly rather than calculated from geometric assumptions and different imaging modalities. In the silicone phantoms used in our study, the stent diameters were significantly smaller than the diameters indicated on the manufacturers' compliance charts of the post-dilatation balloons **(Supplementary Table 4)**. This illustrates the serious constrainment of overexpanded metallic stents on the post-dilatation balloons. This may be of clinical significance since the inability of the stent balloon to reach its target size during deployment of the stent and subsequent elastic recoil are two important contributory factors towards stent underdeployment[22]. The findings support the recommendation that adequately sized balloons and pressures are necessary to facilitate adequate expansion.

The results of the mechanical performance of overexpanded stents as the stent diameter increases in size from 4.00 mm to 6.00 mm provide interesting insights. The effect on the mechanical response in overexpanded stents is still unknown and may be difficult to predict[5]. It has been shown previously that extremely oversized post-dilation, for example caused by kissing post-dilation, considerably modifies the strut configuration[11]. There are concerns that distortion of the stent crowns may occur with stent overexpansion with several potential risks – a change in the mechanical response of the stent, a decrease in the stent resistance to fatigue, and damage to polymer coating[9]. The graphical data in **Figure 4A** suggest that, despite overexpansion, the radial strength would not be affected, as the stent size increased after overexpansion and in fact increases when the diameter reaches 6.00 mm.

This is potentially advantageous, as radial strength is a key component towards eliminating acute elastic recoil post stenting. The higher radial strength may be attributed to a change in the geometrical arrangement of the stent struts. The struts exhibit a "column-like" effect as the circumferential struts straighten out and lose their curved interlinked architecture, resulting in an increased resistance to radial forces. Such a finding was demonstrated in a crown deformation analysis of the stent struts after post-dilation by Foin et al[4]. At 6 mm, the stent segments would have been stretched outwards to their limits and nearly straightened out. This extreme state may contribute to an increase in radial strength. Another explanation for the increase in radial strength can be attributed to the decrease in stent length as stents approach their expansion limit. The radial strength values are normalised to stent length (N/mm) so stent length impacts on these values.

There was a decrease in the stent recoil as the stent expanded from 4.00 mm towards 6.00 mm. This finding may be expected, as mechanically the more "column-like" structure of the struts at larger sizes is less likely to recoil than a "spring-like" shape of a "v" at smaller sizes. Stent length change can be unpredictable, as it is a complex function that is dependent on many variables such as the method of deployment, type of balloon used, manner of dilation and final stent diameter.

To our knowledge, this is the first time that bench testing has compared the two post-dilation strategies in an overexpansion model and evaluated the mechanical performance of DES overexpansion. In addition, we have performed advanced finite element computer simulations of the complete stenting procedures. These simulations were based on predetermined pressures and diameters of balloons and stents used in a virtual stent model for every step during the deployment sequence and with assessment of the final stent outcomes **(Figure 5A)**. The results confirmed the experimental findings and provided insights during the balloon inflation during FKBD and additional information on the resulting forces exerted on the stent by the vascular wall. In summary, these simulations revealed that the use of POT results in a highly uniform distribution of these contactile forces in contrast to the FKBD **(Figure 5B, Figure 5C)**.

Limitations

The limitations of our study are inherent to bench testing. Firstly, our data refer to *in vitro* stent deployments performed in standard

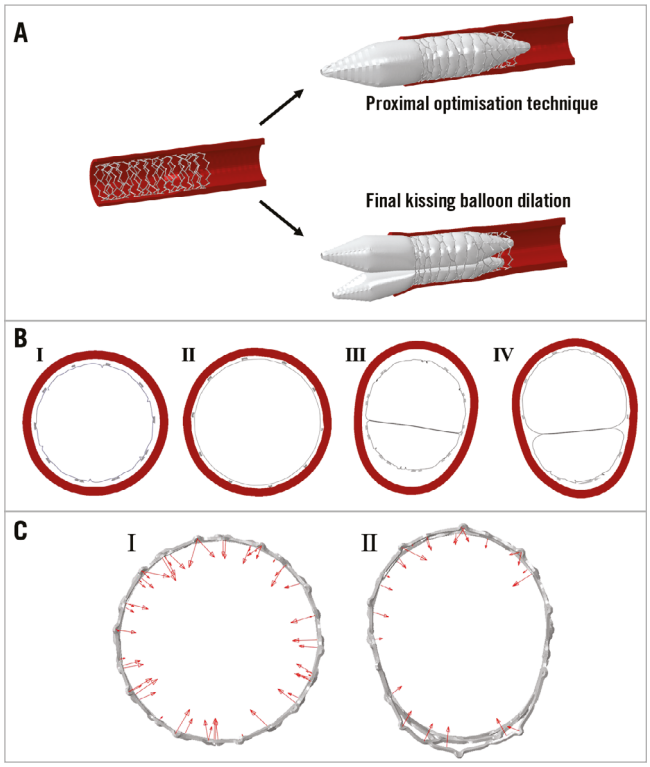

Figure 5. *Computer simulations of the stenting procedures. A) Different models used for overexpansion. This figure illustrates the two types of overexpansion strategy, namely the proximal optimisation technique (POT) and final kissing balloon dilation (FKBD), studied in both the bench testing and modelling process. B) Cross-section of stents (proximal edge) post dilation in virtual testing. Left to right: I) POT-SC/LP with some malapposition, II) POT-SC/SP with full apposition, III) FKBD-OS/LP with ellipticity and some malapposition, IV) FKBD-OS/SP with ellipticity and some malapposition. FKBD: final kissing balloon dilation; LP: low pressure; OS: optimally sized; POT: proximal optimisation technique; SC: semi-compliant; SP: standard pressure C) Distribution of contactile forces on stents after virtual implantation. The cross-section of a computer simulation post POT (I). The arrows indicate the uniform distribution of the contact forces seen during the computer modelling. The right image (II) shows the cross-section of a computer simulation post FKBD. The arrows indicate a non-uniform distribution of the contact forces seen during the computer modelling.*

laboratory environments in silicone phantom models. *In vivo* behaviour and stent artery response during stent deployment of different sizes in diseased arterial walls constraining the stents in a real-world clinical setting may be different. Other vascular characteristics including vascular wall stiffness, calcification, plaque characteristics and distortion, as well as more complex procedures involving bifurcation and overlapping stents, may affect the resultant expansion of stents deployed in a real-world setting. Secondly, assessment of the side branch in the bifurcation lesion was not available. This is because the effect of kissing balloon dilation in improving blood flow to the side branch during bifurcation stenting has been previously studied[8,21,23,24]. However, in left main stenting, the effect of POT for overexpansion has not been widely studied as it is not routinely carried out, since most operators would consider kissing balloon dilation adequate to achieve optimal stent apposition in the main branch. The main aim of this study was to evaluate the impact of different approaches, namely POT and FKBD, in achieving full apposition in large left main vessels and to compare the impact of POT and FKBD on the main vessel. This is especially important as the left main diameter is generally underestimated and the maximum overexpansion diameters of the stents commonly used in the catheterisation laboratory are unknown to operators. Thirdly, our sample size is relatively small. One stent design and size was tested and no claim on overexpansion of other sizes and designs can be made. Further studies are indicated to perform similar investigations for other stent designs and diameters and to assess long-term structural integrity. Lastly, we have studied POT as a separate entity from FKBD though in reality POT is also frequently performed with FKBD. In our bench testing scenario, while we assume that single use of POT is equivalent to the use of POT with intermediate FKBD, the results still support the recommendation that POT should be the final step regardless of whether FKBD is performed in cases of stent overexpansion.

Conclusions

In conclusion, our study shows that POT but not FKBD can expand the platinum-chromium 4.00 mm stent beyond the overexpansion limit of 5.75 mm with optimal stent apposition and performance in bench testing. In PCI involving relatively larger vessel diameters, such as left main stenting, POT may be the technique of first choice to achieve optimal stent expansion but requires adequately sized balloons with high pressures. The impact on the mechanical performance of the stents after overexpansion would merit further evaluation.

Impact on daily practice

For left main percutaneous coronary intervention (PCI) which is sometimes up to 6 mm in diameter, full pressure (16 atm) large size non-compliant balloons are necessary during the proximal optimisation technique (POT) to achieve a predicted stent diameter of 6 mm and avoid malapposition seen in different final kissing balloon post-dilatation approaches. Platinium-chromium stents maintain their mechanical characteristics at these diameters.

Funding

This research was supported by a research grant from Boston Scientific.

Conflict of interest statement

R.J. van Geuns has received speakers fees from Boston Scientific. The other authors have no conflicts of interest to declare.

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Supplementary data

Supplementary Appendix. Methodology.

Supplementary Table 1. Stent measurements groups 1-6.

Supplementary Table 2. Stent performance measurements.

Supplementary Table 3. Stent performance at overexpansion limits - surface to artery ratio.

Supplementary Table 4. Compliance table of stents/balloons used.

Supplementary Figure 1. Illustration of the bench testing methods performed.

The supplementary data are published online at: www.asiaintervention.org

Supplementary data

Supplementary Appendix. Methodology

The 4.00 mm SYNERGY II stent was used in this study. The SYNERGY II 4.00 mm stent was used based on its unique large vessel design with an increased number of cells and peaks. This results in a labelled post-dilation limit of 5.75 mm which is within the range of most diameters of the left main coronary artery [25]. For FKBD, the 4.00 mm and 5.00 mm balloons were used to achieve a final diameter of 6.00 mm in accordance to Finet's law which states that the diameter of the main branch is related to the two distal branches: diameter of main branch=2/3 (diameter of main distal branch+diameter of side branch) [26]. However, these balloon sizes are not frequently employed; therefore, we also included a model using FKBD with more usual (but undersized) balloon sizes (3.50 and 4.00 mm). FKBD has been studied in the expansion of large calibre proximal vessels without overdilating smaller vessels distal to the bifurcation site [27].

All stents were deployed in an aqueous bath at standard temperature of 37+/-1 degrees Celsius. Stent strut apposition and expansion were evaluated by implanting the stents in silicone tube phantom models. The phantoms had elastic properties that allowed stretching of the material beyond the nominal diameter. Each stent was distally fixated in a 5.00 mm silicone tube. Both the stent and 5.00 mm silicone tube are housed in an outer 6.00 mm silicone tube to accommodate expansion of the proximal stents. Each stent was first deployed using the stent delivery system catheter at rated burst pressure (16 atm) **(Supplementary Figure 1A)**. The distal and proximal stent was then post-dilated in a sequential manner using the semi-compliant (SC) Apex 5.00 mm

balloon at rated burst pressure of 12 atm **(Supplementary Figure 1B, Supplementary Figure 1C)**. Finally, different approaches were used for proximal post-dilation in a 6.00 mm tube **(Supplementary Figure 1D, Supplementary Figure 1E)**.

Supplementary Figure 1. Illustration of the bench testing methods performed.

A) Initial deployment of the stents. The SYNERGY 4.0x28 mm stents were first deployed using the stent delivery system catheter at rated burst pressure (16 atm). Each stent was distally fixated in a 5.00 mm silicone tube. Both the stent and 5.00 mm silicone tube are housed in an outer 6.00 mm silicone tube to accommodate expansion of the proximal stents.

B) Post-dilation of distal end of SYNERGY II stent.

The distal end of the stent was post-dilated with an Apex 5.0x15 mm semi-compliant balloon at rated burst pressure (12 atm) to ensure that the stent was well apposed to the 5 mm tubing. During the post-dilation of the distal end, the proximal end was not in contact with the tubing.

C) Post-dilation of proximal end of SYNERGY II stent.

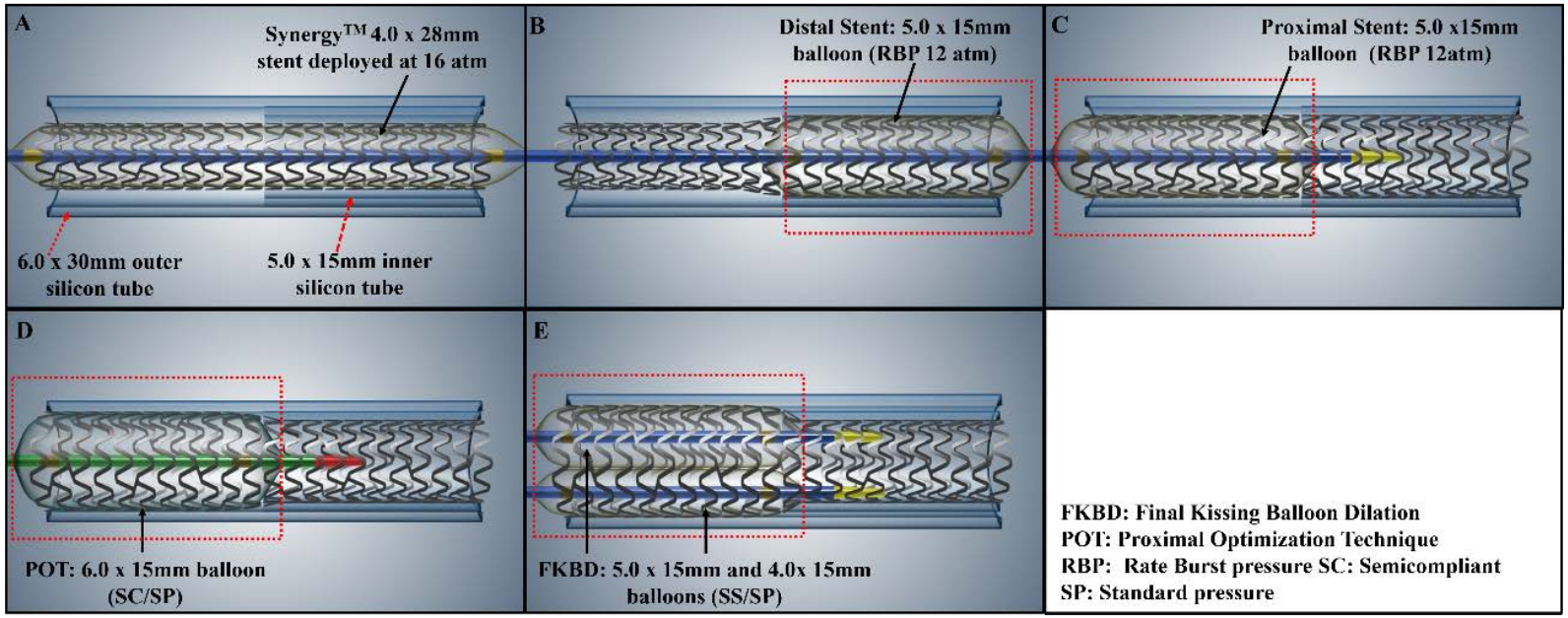
The proximal end of the stent was post-dilated such that the proximal end of the stent was aligned with the proximal end of the 6 mm tube. An Apex 5.0x15 mm semi-compliant balloon at rated burst pressure of 12 atm was used.

D) Proximal optimisation technique (POT).

POT using the 6.0x15 mm Maverick XL or NC Emerge at rated burst pressure of 14 atm was one of the post-dilation methods used.

E) Final kissing balloon dilation (FBKD).

Final kissing balloon dilation with 5.0x15 mm and 4.0x15 mm balloons (low pressure [LP] of 4 atm and standard pressure [SP] of 12 atm were used separately). A combination of 4.0x15 mm and 3.5x15 mm balloons was also used in an “undersized” model.


A
Synergy™ 4.0 x 28mm stent deployed at 16 atm
6.0 x 30mm outer silicon tube
5.0 x 15mm inner silicon tube
B
Distal Stent: 5.0 x 15mm balloon (RBP 12 atm)
C
Proximal Stent: 5.0 x15mm balloon (RBP 12atm)
D
POT: 6.0 x 15mm balloon (SC/SP)
E
FKBD: 5.0 x 15mm and 4.0x 15mm balloons (SS/SP)
FKBD: Final Kissing Balloon Dilation
POT: Proximal Optimization Technique
RBP: Rate Burst pressure SC: Semicompliant
SP: Standard pressure

Stent measurements

A precalibrated Keyence VHX 100 Measurement Scope (Keyence Corporation, Osaka, Japan) was used to obtain the following stent measurements at the proximal stent end after final dilation: 1) stent inner diameter (ID) and outer diameter (OD) with maximum and minimum values for oval stents, 2) stent inner and outer area (calculated based on the dimensions of the stent ID, stent OD, 3) tube inner diameter and area with corresponding maximum and minimum values for oval stents, 4) malapposition area (MA/mm^2)=tube ID area–stent OD area, 5) ellipticity index (EI)=maximum stent inner diameter/minimum stent inner diameter. The circular and oval stents were measured using a 3-point and 2 reference point interpolation method, respectively, for stent maximum and minimum diameters. The stent area was calculated by tracing for oval stents and a 3-point method was used for circular stents.

Mechanical stent performance

Forty 4.0x16 mm stent samples were tested in four groups for radial strength and stent length at 4.0 mm diameter (control group) and at 5.00 mm, 5.75 mm and 6.00 mm diameters (overexpanded groups). Stent length was also captured from these stents as it is an input factor in the radial strength calculation (force/length). The average length values from these groups were also used to calculate vessel area at each diameter in the SAR calculation. The recoil was measured sequentially from the same 10 stents deployed to 4.00 mm, then post-dilated to 5.00 mm, 5.75 mm, and finally to 6.00 mm.

The radial strength or maximum compression resistance of the stent was evaluated by the RX750 Radial Compression Tester (Machine Solutions Inc., Flagstaff, AZ, USA), and the radial strength (N/mm) was calculated by a ratio of peak hoop strength (N) to stent length (mm). Measurements for the length and elastic recoil for each stent after final dilation were quantified using a 3D optical contactless machine (SmartScope® MVP; OGP, Rochester, NY, USA). The amount of elastic recoil was calculated by comparing the stent inner diameters after expanding the stent to a target outer diameter and then deflating the stent (% recoil=(inflated ID- final ID)/inflated ID) * 100). Percentage surface to artery ratio (% SAR) was calculated as a ratio of stent outer surface area to vessel area (outer diameter d * π * stent length) multiplied by 100.

Supplementary Table 1. Stent measurements groups 1-6.

A. Group 1 - proximal optimisation technique - semi-compliant/low pressure (POT-SC/LP).

	Stent ID			Stent OD			Tube ID max			Malapposed area	
Stent sample	Stent ID max (mm)	Stent ID min (mm)	Stent ID area (mm^2)	Stent OD max (mm)	Stent OD min (mm)	Stent OD area (mm^2)	Tube ID max (mm)	Tube ID min (mm)	Tube ID area (mm^2)	Malapposed area ID/ID (mm^2)	Malapposed area OD/ID (mm^2)
44	4.95	4.95	19.06	5.07	5.07	20.20	6.38	5.93	29.17	10.11	8.97
45	5.05	5.05	19.94	5.17	5.17	21.11	6.55	5.66	28.85	8.91	7.74
46	5.05	5.05	19.82	5.19	5.19	21.11	6.16	6.16	29.60	9.78	8.49
Average	5.02	5.02	19.61	5.14	5.14	20.81	6.36	5.92	29.21	9.60	8.40
SD	0.06	0.06	0.48	0.06	0.06	0.53	0.20	0.25	0.38	0.62	0.62

B. Group 2 - proximal optimisation technique - semi-compliant/standard pressure (POT-SC/SP).

	Stent ID			Stent OD			Tube ID max			Malapposed area	
Stent sample	Stent ID max (mm)	Stent ID min (mm)	Stent ID area (mm^2)	Stent OD max (mm)	Stent OD min (mm)	Stent OD area (mm^2)	Tube ID max (mm)	Tube ID min (mm)	Tube ID area (mm^2)	Malapposed area ID/ID (mm^2)	Malapposed area OD/ID (mm^2)
24	5.96	5.96	27.78	6.09	6.09	29.00	6.23	6.23	29.41	1.63	0.41
25	5.86	5.86	26.89	6.03	6.03	28.54	6.20	6.20	29.95	3.06	1.41
26	5.86	5.86	26.89	6.03	6.03	28.69	6.18	6.18	29.95	3.06	1.26
47	5.85	5.85	26.82	5.95	5.95	28.02	6.16	6.16	29.73	2.91	1.71
48	5.86	5.86	26.97	5.99	5.99	28.17	6.13	6.13	29.26	2.29	1.09
49	5.89	5.89	26.97	5.98	5.98	28.32	6.22	6.00	29.06	2.09	0.74
50	5.84	5.84	26.58	5.99	5.99	28.17	6.12	6.12	29.16	2.58	0.99
51	5.95	5.95	27.72	6.07	6.07	28.78	6.21	6.21	29.94	2.22	1.16
52	5.98	5.98	27.87	6.13	6.13	29.40	6.21	6.21	30.20	2.33	0.80
53	5.93	5.93	27.42	6.09	6.09	29.09	6.23	6.23	30.20	2.78	1.11
Average	5.90	5.90	27.19	6.04	6.04	28.62	6.19	6.17	29.69	2.50	1.07
SD	0.05	0.05	0.46	0.06	0.06	0.46	0.04	0.07	0.43	0.47	0.36

C. Group 3 - proximal optimisation technique - non-compliant/high pressure (POT-NC/HP).

	Stent ID			**Stent OD**			**Tube ID max**			**Malapposed area**	
Stent sample	**Stent ID max (mm)**	**Stent ID min (mm)**	**Stent ID area (mm^2)**	**Stent OD max (mm)**	**Stent OD min (mm)**	**Stent OD area (mm^2)**	**Tube ID max (mm)**	**Tube ID min (mm)**	**Tube ID area (mm^2)**	**Malapposed area ID/ID (mm^2)**	**Malapposed area OD/ID (mm^2)**
P10	6.07	6.07	28.72	6.19	6.19	29.98	6.19	6.19	29.98	1.26	0.00
P11	6.13	6.13	29.34	6.29	6.29	31.09	6.29	6.29	31.09	1.75	0.00
P12	6.01	6.01	28.26	6.17	6.17	29.82	6.17	6.17	29.82	1.56	0.00
Average	**6.07**	**6.07**	**28.77**	**6.22**	**6.22**	**30.30**	**6.22**	**6.22**	**30.30**	**1.52**	**0.00**
SD	0.06	0.06	0.54	0.06	0.06	0.69	0.06	0.06	0.69	0.25	0.00

D. Group 4 - final kissing balloon dilation - undersized/standard pressure (FKBD-US/SP).

	Stent ID			Stent OD			Tube ID max			Malapposed area	
Stent number	Stent ID max (mm)	Stent ID min (mm)	Stent ID area (mm^2)	Stent OD max (mm)	Stent OD min (mm)	Stent OD area (mm^2)	Tube ID max (mm)	Tube ID min (mm)	Tube ID area (mm^2)	Malapposed area ID/ID (mm^2)	Malapposed area OD/ID (mm^2)
18	6.36	4.15	21.90	6.52	4.40	23.50	6.90	5.42	28.68	6.78	5.18
19	6.37	4.09	21.61	6.62	4.30	22.96	6.62	5.64	29.10	7.49	6.14
20	6.15	4.06	20.63	6.38	4.26	21.88	6.58	5.73	29.15	8.52	7.27
Average	6.29	4.10	21.38	6.51	4.32	22.78	6.70	5.60	28.98	7.60	6.20
SD	0.12	0.05	0.67	0.12	0.07	0.82	0.17	0.16	0.26	0.87	1.05

E. Group 5 - final kissing balloon dilation - optimally sized/low pressure (FKBD-OS/LP).

	Stent ID			Stent OD			Tube ID max			Malapposed area	
Stent number	Stent ID max (mm)	Stent ID min (mm)	Stent ID area (mm^2)	Stent OD max (mm)	Stent OD min (mm)	Stent OD area (mm^2)	Tube ID max (mm)	Tube ID min (mm)	Tube ID area (mm^2)	Malapposed area ID/ID (mm^2)	Malapposed area OD/ID (mm^2)
15	5.45	4.64	19.81	5.66	4.85	20.94	6.47	5.90	29.25	9.44	8.31
16	5.36	4.63	19.48	5.52	4.82	20.64	6.54	5.78	28.97	9.49	8.33
17	5.61	4.61	19.68	5.84	4.81	21.02	6.49	5.84	29.09	9.41	8.07
Average	5.47	4.63	19.66	5.67	4.83	20.87	6.50	5.84	29.10	9.45	8.24
SD	0.13	0.02	0.17	0.16	0.02	0.20	0.04	0.06	0.14	0.04	0.14

F. Group 6 - final kissing balloon dilation - optimally sized/standard pressure (FKBD-OS/SP).

	Stent ID			Stent OD			Tube ID max			Malapposed area	
Stent sample number	Stent ID max (mm)	Stent ID min (mm)	Stent ID area (mm^2)	Stent OD max (mm)	Stent OD min (mm)	Stent OD area (mm^2)	Tube ID max (mm)	Tube ID min (mm)	Tube ID area (mm^2)	Malapposed area ID/ID (mm^2)	Malapposed area OD/ID (mm^2)
2	6.60	4.72	25.53	6.87	4.89	26.74	6.87	5.24	28.54	3.01	1.80
3	6.57	4.68	25.33	6.77	4.98	27.05	6.77	5.42	29.29	3.96	2.24
4	6.82	4.69	26.24	7.03	4.89	27.88	7.03	5.10	29.10	2.86	1.22
Average	6.66	4.70	25.70	6.89	4.92	27.22	6.89	5.25	28.98	3.28	1.75
SD	0.14	0.02	0.48	0.13	0.05	0.59	0.13	0.16	0.39	0.60	0.51

Supplementary Table 2. Stent performance measurements.

A. SYNERGY 4x16 mm radial strength, as measured by average maximum compression resistance (hoop force/length: N/mm).

Sample	4 mm maximum compression resistance (N/mm)	5 mm maximum compression resistance (N/mm)	5.75 mm maximum compression resistance (N/mm)	6 mm maximum compression resistance (N/mm)
1.00	0.26	0.27	0.26	0.36
2.00	0.24	0.28	0.30	0.38
3.00	0.25	0.30	0.24	0.37
4.00	0.26	0.28	0.28	0.42
5.00	0.24	0.26	0.29	0.36
6.00	0.28	0.25	0.30	0.31
7.00	0.25	0.26	0.38	0.44
8.00	0.28	0.26	0.26	0.43
9.00	0.28	0.25	0.23	0.37
10.00	0.25	0.30	0.27	0.34
Average	**0.26**	**0.27**	**0.28**	**0.38**
SD	**0.01**	**0.02**	**0.04**	**0.04**

B. SYNERGY 4.0x16 mm recoil.

	% ID recoil			
unit #	**4.0 mm % recoil**	**5.0 mm % recoil**	**5.75 mm % recoil**	**6.0 mm % recoil**
1	3.5%	0.4%	0.3%	1.8%
2	2.7%	2.0%	1.2%	1.2%
3	2.2%	1.6%	1.2%	1.7%
4	4.4%	1.8%	2.2%	2.0%
5	3.0%	1.6%	1.7%	2.0%
6	2.2%	1.8%	0.9%	0.8%
7	1.7%	2.0%	1.5%	0.7%
8	2.0%	1.0%	1.2%	0.5%
9	3.2%	1.4%	1.4%	2.0%
10	3.7%	2.6%	1.2%	1.2%
Average % recoil	**2.9%**	**1.6%**	**1.3%**	**1.4%**
SD	**0.9%**	**0.6%**	**0.5%**	**0.6%**

C. SYNERGY 4.0x16 mm SAR calculation (%).

Stent ID (mm)	**Stent OD (mm)**	**Stent length (mm)**	**Vessel area (mm^2)**	**SAR %**
4.0	4.17	16.1	210	14.2%
5.0	5.17	17.5	284	10.5%
5.75	5.92	16.8	313	9.5%
6.0	6.17	16.4	317	9.4%

D. SYNERGY 4.0x16 mm length (mm).

Sample	4.0 mm length (mm)	5.0 mm length (mm)	5.75 mm length (mm)	6.0 mm length (mm)
1.00	16.10	16.82	17.35	16.20
2.00	15.80	17.24	17.10	16.32
3.00	16.03	16.61	17.45	16.30
4.00	16.21	17.24	16.67	16.55
5.00	15.90	17.70	16.30	16.03
6.00	16.18	18.05	16.05	16.95
7.00	16.28	17.77	16.29	16.02
8.00	16.03	17.78	16.63	16.35
9.00	16.19	17.96	17.67	16.38
10.00	15.82	17.45	16.93	16.58
Average	**16.05**	**17.46**	**16.84**	**16.37**
SD	**0.17**	**0.48**	**0.55**	**0.28**

Supplementary Table 3. Stent performance at overexpansion limits - surface to artery ratio.

			Stent length (mm)		Radial strength (maximum hoop force / length [N/mm])		% Surface to artery ratio		% Stent recoil	
Stent model	Sample size	Stent diameter (mm)	Average	Standard deviation	Average	Standard deviation	Vessel area (mm^2)	SAR %	Average	Standard deviation
SYNERGY II 4.0x16 mm	10	4.0	16.1	0.2	0.26	0.01	210	14.2%	2.9	0.9
SYNERGY II 4.0x16 mm	10	5.0	17.5	0.5	0.27	0.02	283	10.5%	1.6	0.6
SYNERGY II 4.0x16 mm	10	5.75	16.8	0.6	0.28	0.04	313	9.5%	1.3	0.5
SYNERGY II 4.0x16 mm	10	6.0	16.4	0.3	0.38	0.04	317	9.4%	1.4	0.6

Supplementary Table 4. Compliance table of stents/balloons used*.

Stent/balloon size		Pressure		Stent/balloon dimensions (mm)	
		(atm)	(kPa)		
SYNERGY II 4.0 mm	Nominal	11.0	1,117	ID 4.06	OD 4.24
	RBP	16.0	1,620	ID 4.30	OD 4.48
NC Quantum Apex 5.0 mm	Nominal	12.0	1,216	4.95	
	RBP	18.0	1,824	5.15	
Apex 4.0 mm	Low	4.0	405	3.80	
	Nominal	6.0	608	3.96	
	RBP	12.0	1,216	4.25	
Apex 5.0 mm	Low	4.0	405	4.79	
	Nominal	6.0	608	4.99	
	RBP	12.0	1216	5.30	
Maverick XL 6.0 mm	Nominal	6.0	608	6.00	
	RBP	14.0	1,419	6.46	
NC Emerge 6.0 mm	Nominal	6.0	608	6.09	
	RBP	14.0	1,419	6.28	

*Source: Boston Scientific, Maple Grove, MN, USA.

ID: inner diameter; OD: outer diameter; RBP: rated burst pressure