International Journal of Cardiology 221 (2016) 171–179

Contents lists available at ScienceDirect

International Journal of Cardiology

journal homepage: www.elsevier.com/locate/ijcard

Over-expansion capacity and stent design model: An update with contemporary DES platforms

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ARTICLE INFO

Article history:
Received 5 February 2016
Received in revised form 23 May 2016
Accepted 21 June 2016
Available online 24 June 2016

Keywords:
DES
Stent
Left main
Expansion

ABSTRACT

Background: Previously, we examined the difference in stent designs across different sizes for six widely used Drug Eluting Stents (DESs).
Although stent post-dilatation to larger diameter is commonly done, typically in the setting of long tapering segment or left-main PCI, there is an increasing recognition that information with regard to the different stent model designs has a critical impact on overexpansion results.
This study aims to provide an update on stent model designs for contemporary DES platforms as well as test overexpansion results under with oversized post-dilatation.
Methods and results: We studied 6 different contemporary commercially available DES platforms: *Synergy, Xience Xpedition, Ultimaster, Orsiro, Resolute Onyx* and *Biomatrix Alpha*. We investigated for each platform the difference in stent designs across different sizes and results obtained after post-expansion with larger balloon sizes. The stents were deployed at nominal diameter and subsequently over expanded using increasingly large post dilatation balloon sizes (4.0, 5.0 and 6.0 mm at 14ATM). Light microscopy was used to measure the changes in stent geometry and lumen diameter after over-expansion.
For each respective DES platform, the MLD observed after overexpansion of the largest stent size available with a 6.0 mm balloon was 5.7 mm for *Synergy*, 5.6 mm for *Xience*, 5.2 mm for *Orsiro*, 5.8 mm for *Ultimaster*, 5.5 mm for 4 mm *Onyx* (5.9 mm for the 5 mm XL size) and 5.8 mm for BioMatrix *Chroma*.
Conclusion: This update presents valuable novel insights that may be helpful for careful selection of stent size for contemporary DES based on model designs. Such information is especially critical in left main bifurcation stenosis treatment where overexpansion to larger oversized diameter may be required to ensure full stent apposition.

1. Introduction

DESs are nowadays commonly used in PCI for treatment of left-main and long bifurcated segments. Due to the difference in lumen diameter between the vessel and the stent size in some coronary arteries, proximal post-expansion of the stent is normally necessary to match proximal reference diameter and optimize stent apposition.

As stent post-dilatation is commonly performed, typically with large over-expansion in the setting of long tapering vessel segment, there is an increasing recognition that information with regard to the different stent model designs can have a critical impact on overexpansion results.

Incomplete stent apposition has been associated with increased risk of in stent restenosis (ISR) and stent thrombosis (1). Previously, we examined the difference in stent designs across different sizes for 6 widely used Drug Eluting Stents (DESs) (2).

We tested overexpansion capacity of each stent design with post-dilatation using balloon diameters up to 6 mm and showed how, in absence of this critically important information, stents implanted in segments with major changes in vessel diameter have the potential to become grossly overstretched and to remain incompletely apposed (2–4).

This study aims to provide an update on stent model designs for contemporary DES platforms as well as test overexpansion results under with oversized post-dilatation.

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http://dx.doi.org/10.1016/j.ijcard.2016.06.097

2. Method

2.1. Stent design nomenclature

By convention, for DES platforms with only two designs, these were named here as *small vessel* and *large vessel* model designs. For the *Synergy* platform which has three designs, these were termed *small*, *medium/workhorse* and *large vessel* designs. It has to be noted that this terminology was used for a uniform presentation in this manuscript and manufacturers may use a different nomenclature. A *Crown* or *Peak* is defined as 2 adjacent struts forming an angle. A complete *stent Ring* is formed by a number of adjacent crowns which give the stent its expansion capacity from a crimping state. Rings are connected to each other longitudinally by *Connectors* and a *stent Cell* is defined as the area enclosed by a pair of connectors and crowns (2).

3. DES overexpansion experiments

Six commercially available drug-eluting stents (DESs) were analysed: the everolimus-eluting PtCr SYNERGY™ (Boston Scientific, Natick, MA, USA), everolimus-eluting Cobalt Chromium (CoCr) XIENCE PRIME/XPEDITION™ (Abbott Vascular, Santa Clara, *CA*, USA), the ULTIMASTER® - Drug eluting stent (Terumo Corporation, Shibuya-ku, Tokyo, Japan), the ORSIRO Sirolimus Eluting Stent (BIOTRONIK AG, Berlin, Germany), the Resolute ONYX™ Zotarolimus-Eluting Stent (Medtronic, *CA*, US) and the BioMatrix Alpha/Chroma CoCr Stent Platform (Biosensors Interventional Technologies, Singapore) (Fig. 2). Samples of different stent sizes/models were deployed *in vitro* at nominal pressure (NP). Subsequently, over-expansion results for each design was tested with successive post-dilations using a 4.0 × 12 and a 5.0 × 12 non-compliant balloons (Expected Diameter at 14 ATM = 5.02 mm) (NC Quantum Apex; Boston Scientific, Natick, MA, USA) inflated at 14 ATM; for the largest designs, we used first a 5.0 × 12 non-compliant balloon followed by a 6.0 × 15 mm semi-compliant balloon (Maverick XL; Boston Scientific, Natick, MA, USA) with a pressure of 14ATM (Expected Diameter at 14 ATM = 6.46 mm). Post-dilation was performed on the proximal segment of the stent with a stent length equivalent to length of the post-dilatation balloon. Final dilations were repeated on the samples a second time to ensure an optimal expansion of the stent struts. For each individual stent diameter, two samples were deployed.

4. Microscope analysis

Stent samples were mounted and analysed using light microscopy (Leica MZ16 FA, Meyer Instruments, Houston, TX, USA). The magnified images of the stents were saved and used for quantitative measurement and analysis of the deformation. Longitudinal and transverse sections of the overexpanded stent at different reference in the proximal and distal sections of the stents were compared to assess the differences after overexpansion of the stents. Fig. 1 shows what parameters were measured from each of the images.

5. MLD and MSA

Cross-Sectional minimal lumen diameter was defined as the minimal lumen diameter (MLD) measured on the cross-sectional images of the stent from one strut edge to the opposite strut edge. The minimal stent area (MSA) was defined to be the cross-sectional inner lumen stent area excluding the stent struts. Lumen diameters were also derived from the measured MSA to compare with the MLD values measured from the cross sectional images.

On the proximal (over expanded) side, the lumen diameter was measured both at the proximal edge of the stent as well as 5 mm distally from the proximal edge. Lumen diameter was also measured using the side-view. Each measurement of MLD and MSA was repeated twice. The result provided was an average of measures on two samples with standard deviation.

6. Cell opening

The change in cell opening was estimated for each stent design after being deployed at nominal pressure (NP) as well as after overexpansion. Cell opening was measured using the longitudinal view and was estimated using a circle with its circumference fitted within the stent cell struts.

For a stent that has been ideally deployed in a vessel, the radius of the circle fitted within the cell represents the maximal distance between the arterial tissue and a neighbouring stent strut. An average of three measures was taken at NP and at maximal dilation (over expanded). The maximal cell opening at maximal dilation was also noted down and this occurs at the transition between the over expanded stent portion and the stent portion at NP. To ensure that the maximal dilation at the transition was measured, the stent was reoriented to be able to view the stent cells in the transition region.

7. Crown angle analysis

To study the effects of over expansion on strut deformation, the longitudinal view was used to measure the angle between 2 adjacent struts within a crown, avoiding crowns attached to a connector. Crown Angle was measured at NP and at over. An average of 3 measures was taken at NP and at post dilation (over expanded).

8. Results

8.1. Stent platforms and model designs

Of the six DES platforms investigated, four of them: *Xience, Orsiro, Ultimaster* and *BioMatrix A/Chroma* had two designs to cover the entire range of their diameter while *Synergy* has three designs and *Onyx* has four designs. For *Synergy,* we tested stents with nominal diameters of *2.75, 3.0* and 4.0 mm. For *Xience* and *BioMatrix A/Chroma*, stents with nominal diameters of 3.0 (SV Model) and 3.5 mm (LV Model) were tested. For *Orsiro* and *Ultimaster* we tested stents with nominal diameters of 3.0 and 4.0 mm. For *Onyx*, stents with nominal diameters of 2.5, 3.0, 4.0 and 5.0 mm were tested. Details of each DES design can be found in Table 1.

8.2. Maximal expansion capacity

Table 2 shows the obtained measurements of lumen diameter from both the cross-sectional and longitudinal images. Most stents were able to expand well above their labelled maximal stent diameter using larger post-dilatation balloons. Achieved MLD (considering minimal inner lumen obtained, excluding struts) after overexpansion was between 25% and 78% higher than the nominal stent diameter and average increase was 56%.

MLD observed after overexpansion of small-vessel workhorse (below 2.5 mm size) was 3.6 mm for *Synergy* and 3.3 mm for *Onyx* after post-expansion with a maximal non-compliant balloon of 4.0 mm at 14 atm. For medium-vessel workhorse (3 mm diameter stents), the MLD observed after overexpansion with a maximal non-complaint 5.0 mm balloon at 14ATM was 4.2 mm for *Synergy*, 4.0 mm for *Xience*, 4.0 mm for *Orsiro*, 4.3 mm for *Ultimaster*, 4.3 mm for *Onyx* and 4.1 mm for *Chroma*. For large-vessel workhorse (4.0 mm diameter stents, 3.5 mm for *Chroma*), the MLD observed after overexpansion with a 6.0 mm semi compliant balloon at 14ATM was 5.7 mm for *Synergy*, 5.6 mm for *Xience*, 5.2 mm for *Orsiro*, 5.8 mm for *Ultimaster*, 5.5 mm for *Onyx* and 5.8 mm for *Chroma*. Additionally, we tested the *Onyx* extra-large design which is available up to 5.0 mm size and MLD after overexpansion with 6.0 mm semi compliant balloon at 14ATM was 5.9 mm.

The LD derived from MSA also showed very good agreement with direct LD measurement, with the maximum difference being 0.2 mm (Table 2).

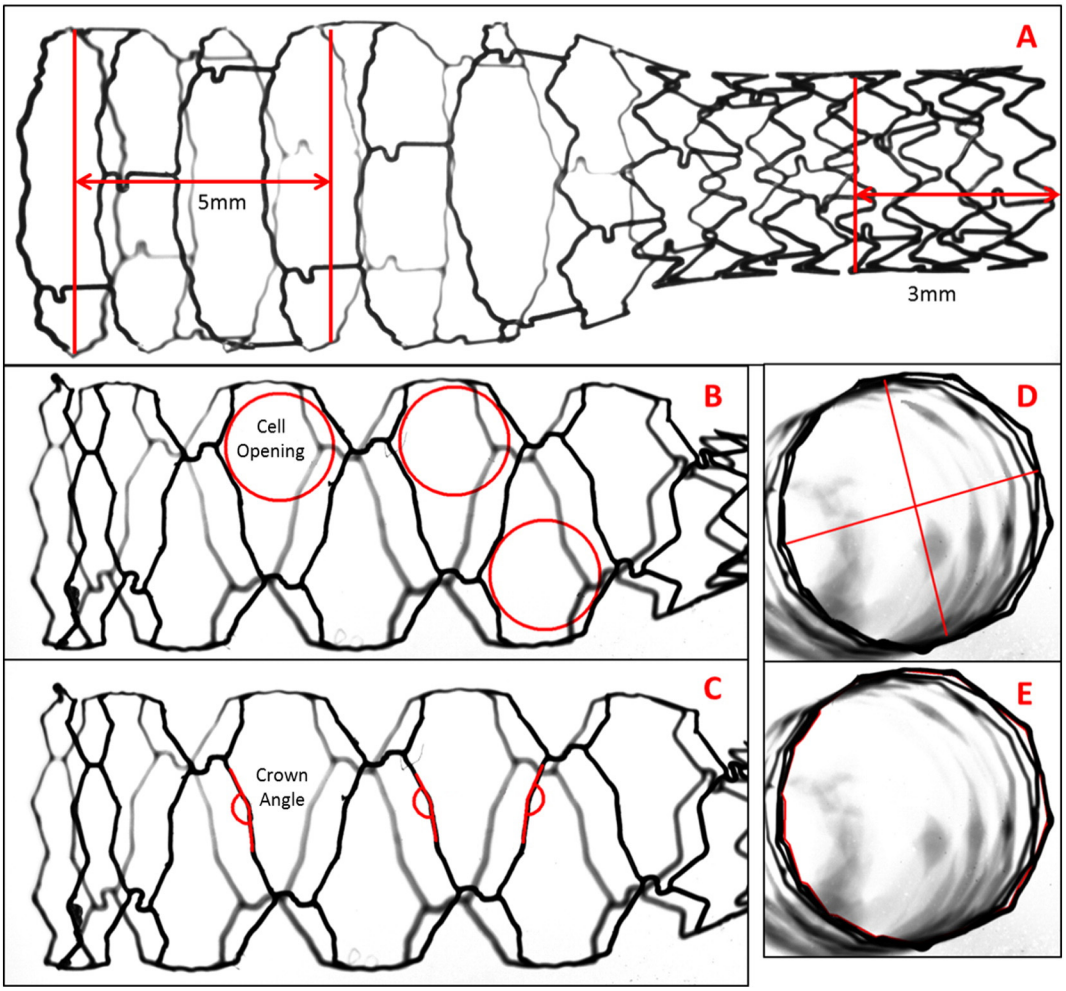


Fig. 1. Methods of Measurements: Minimal Lumen Diameter (MLD) is measured from the side view at the edge and 5 mm distal from the overexpanded edge (A). Cell opening diameter, including a cell opening diameter at the stent transition (B) and crown angle (C) are also measured from the side view. From the cross-sectional view, the Stent Luminal Diameter on 2 perpendicular axis (D) and the minimal stent lumen Area (E) are also measured.

8.3. Cell opening

Over expansion of stents are characterized by important strut distortion and large cell enlargements depending on the stent structure designs. Larger average distances between adjacent struts indicate large gaps in strut scaffolding which increases the risk of plaque prolapsing between struts, reducing drug delivery efficacy per unit wall surface area.

Diameter cell opening was assessed for each design and compared between maximal expansion and nominal pressure deployment. For the different platform, cell opening varied based on model design and largely increased after over expansion (Table 3 and Fig. 3).

For cell opening diameter at nominal pressure, the cell openings for *Synergy* were 0.6, 0.8 and 0.8 mm for the small, medium and large designs respectively, for *Xience* the cell openings were 1.1 and 0.9 mm for the medium and large designs respectively, for *Orsiro* the cell openings were 0.6 and 0.8 mm for the small and mid-large designs respectively, for *Ultimaster*, the cell openings were 0.7 and 1.0 mm for the small and mid-large designs respectively, for *Onyx*, the cell openings were 0.9 mm for all diameters and for *Chroma*, the cell openings were 1.1 and 1.0 mm for the medium and large designs respectively.

Cell opening diameter increased by an average of 114% between nominal pressure deployment and over expansion. The percentage increase for *Synergy* was 150, 131 and 145% for the small, medium and large designs respectively, for *Xience* it was 48 and 83% for the medium and large designs respectively, for *Orsiro* it was 164 and 145% for the small and mid-large designs respectively, for *Ultimaster* it was 119 and 123% for the small and mid-large designs respectively, for *Onyx* it was 90, 107, 104 and 89% for the small, medium, large and extra-large designs respectively and for *Chroma* it was 70 and 147% for the medium and large designs respectively.

The largest cell opening diameter was generally observed in the mid-section of the stent at the transition. For *Synergy* it was 1.5, 1.8 and 1.9 mm for the small, medium and large designs respectively, for *Xience* it was 1.6 and 1.7 mm for the medium and large designs respectively, for *Orsiro* it was 1.5 and 2.0 mm for the small and mid-large designs respectively, for *Ultimaster* it was 1.6 and 2.2 mm for the small and mid-large designs respectively, for *Onyx* it was 1.7, 1.8, 1.8 and 1.7 mm for the small, medium, large and extra-large designs respectively and for *Chroma* it was 1.8 and 2.5 mm for the medium and large designs respectively.

8.4. Crown deformations

Increasing the post-dilatation diameter causes the stent struts to progressively straighten with some stent rings becoming almost circular in the post-dilated segment as they approach their stretching limit (Table 3 and Fig. 4).

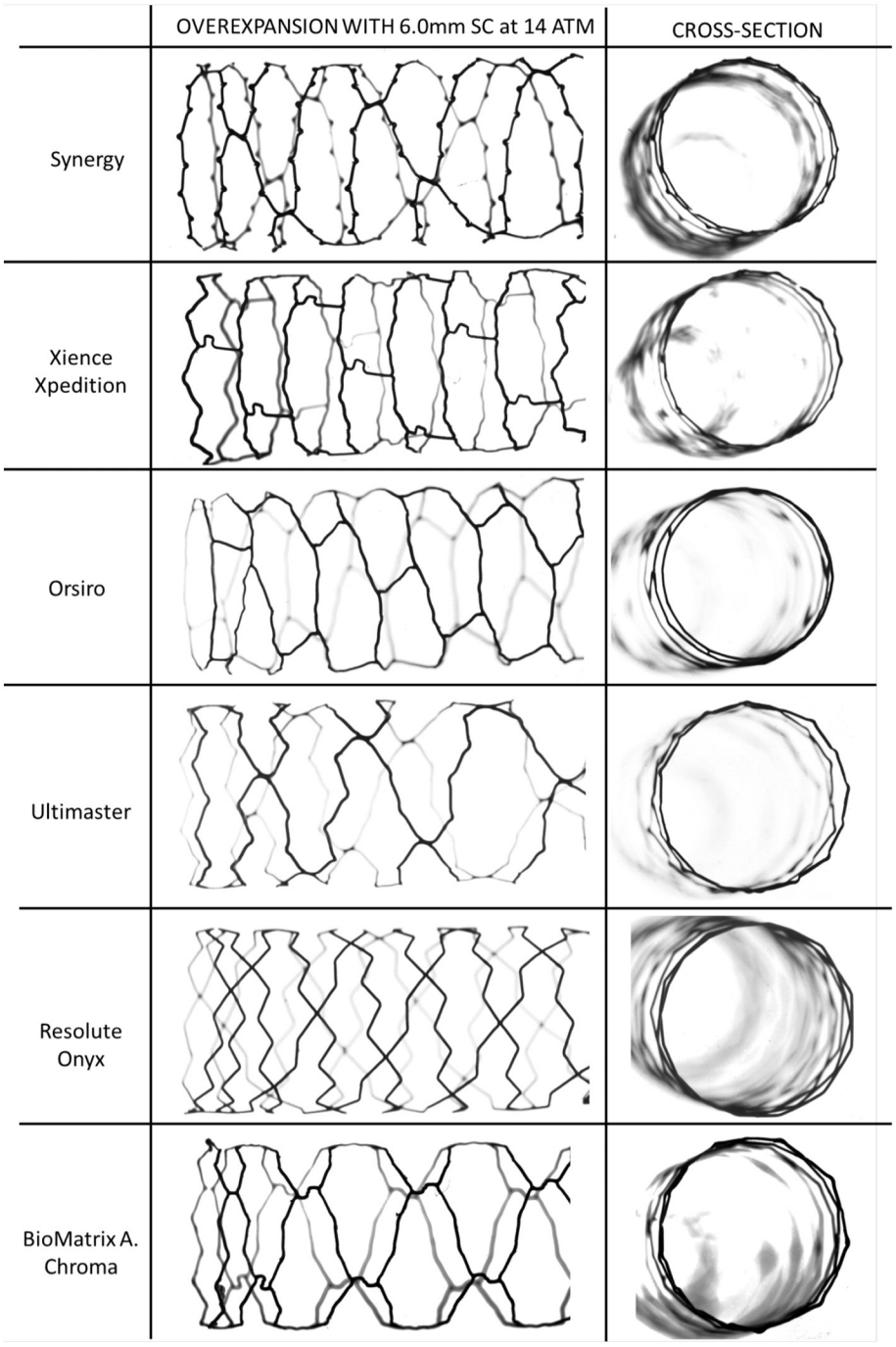


Fig. 2. Largest workhorse designs for each stent platform: Each of the picture shows the longitudinal image as well as the cross sectional image of the largest workhorse design of each platform after over expansion to 6.0 mm.

Over expansion caused noticeable straightening of the stent crown angle from an average crown angle of 77 ± 8° across all stents at nominal pressure deployment to 146 ± 15° after over expansion.

For the largest workhorse designs of all the platforms, *Chroma* showed the largest percentage increase in crown angle at 151% while *Onyx* on the other hand showed the smallest percentage increase in crown angle at 50%.

9. Discussion

In this study, we tested the overexpansion capabilities from six contemporary DES platforms, testing each design of each platform using increasing balloon sizes. Light microscopy was used to assess the morphological changes from nominal deployment to overexpansion. The main findings show that:

- Newer DES designs have similar cut-off diameter between small and large vessel size, and are able to expand largely beyond their nominal diameter.
- Overexpansion not only increases the MLD and MSA, but also increases the cell size and also the straightening of the struts.
- The morphological change in stent varies between stent platforms as well as stent size (model design) for a given platform.

Although normally comprised between 4.5 and 5.0 mm, the average diameter of a left main artery may reach over 5.5 mm in some patients according to some recent imaging studies (5,6), which means most of

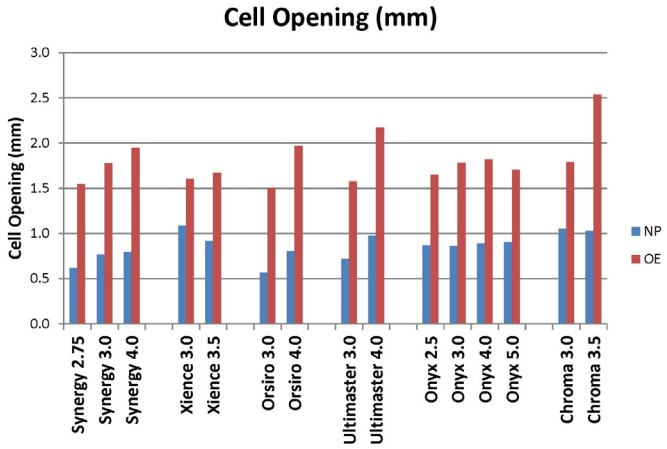


Fig. 3. Cell opening measurements at nominal pressure (NP) deployment and at over expansion (OE): Cell opening values are the average values across 6 measurements. Comparable cell opening values between the platforms and designs are observed at nominal diameter. Overexpansion increased cell opening by more than two folds, which is likely to affect scaffolding and drug delivery.

the current DES platforms are not provided in suitable sizes for those anatomies (currently, only the Taxus and the Resolute Onyx XL are provided in size above 4.5 mm). Other platforms will require post dilatation of at least 0.5 mm beyond their nominal diameter to ensure the optimal apposition of the stent in these anatomies (2,6,7).

We should note the fact that these DESs can be oversized does not imply that it is safe to do so. Indeed approaching physical limit of the stent induces changes in mechanical stiffness and drug delivery, therefore the performance of the device can be completely altered.

To our knowledge, in the main stream DES platforms, only the large size design of the Synergy (4.0 size), Promus Element (4.0 size), Resolute Onyx XL (4.5 and 5.0 size) and Taxus (4.5 and 5.0 size, Boston Scientific) have been labelled for post-expansion beyond 5.0 mm.

Malapposition of stents due to lack of incomplete stent expansion has been known to be a predicator of adverse outcomes (8–10). Although there is a need for overexpansion to treat left main stenosis, data regarding overexpansion beyond labelled recommendation are rarely provided by the manufacturers.

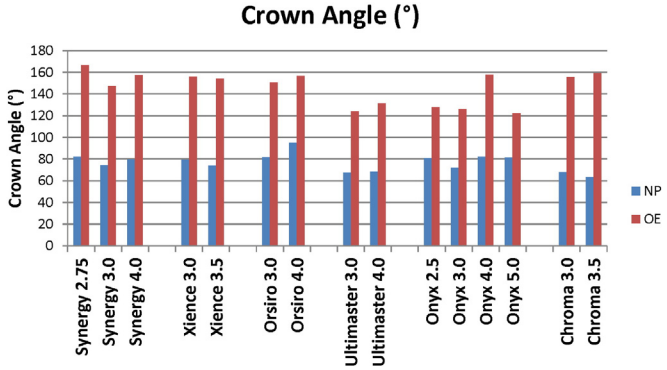


Fig. 4. Crown Angle measurements at Nominal Pressure (NP) deployment and at Over Expansion (OE): The crown angles are measured between adjacent struts that do not have a connector between them. Although at nominal diameter crown angles usually ranged from 63 to 95°, this was increased after overexpansion to over 122°, indicative of how much straightening was present in the crowns after overexpansion.

There have been previous studies done on stent over expansion. A previous study from our group on overexpansion looked at six stent platforms and their morphological changes after overexpansion (2).

This study aimed at applying a similar methodology to look at contemporary DES platforms.

Kissing balloon technique was not investigated in this study. Several experiments showed that Kissing balloon technique, which is commonly employed in bifurcation cases, may lead to severe elliptical stent distortion and even malapposition in some case if used to optimize apposition of the entire proximal stent segment (11–14). A more circular stent cross section is expected after Proximal Optimization Technique (POT). Therefore POT is nowadays recommended not only to optimize the stent before but also as a final step if Simultaneous Kissing Balloon is performed to correct the potential stent distortion caused by the overlap of the 2 balloons (4,11–13,15).

10. Lumen diameter and minimal stent area

In this study, we can see that all stent designs were able to expand well beyond nominal diameter. From the longitudinal measurements, most stents show similar diameters between the proximal over expanded edge and 5 mm distal from the proximal edge, indicating that the stent expanded evenly length-wise. Cross sectional LD measurements show that the MLD is within 0.1 mm of the average LD measured from side-view. This indicates that the overexpansion was even and the stent expanded uniformly.

The general consensus is that the stents should be sized based on the distal diameter of the vessel, especially for bifurcations, using POT for optimal apposition of the proximal side of the vessel (4). Although in an ideal scenario, the stents should be able to achieve a MLD equal to the diameter of the balloon, we see here that this is often not the case, which is in accordance with other reports (1,2,6,16,17). For our study, all large stent designs were post dilated using a 6.0 mm semi-compliant Maverick balloon (Expected Diameter at 14 ATM = 6.46 mm) but the MLD obtained on the stents only ranged from 5.3 mm to 6.0 mm.

As the strut straightens, the hoop force that the balloon has to provide to induce plastic deformation of the stent and limit elastic stent recoil increases. An *in-vivo* study by Berrocal et al. observed more stent recoil in overexpanded stents (18). Minimizing stent recoil is important as it leads to lowered risk of restenosis (19). Another study by Carrozza et al. suggested that an overexpansion of 10–20% above the reference vessel diameter is necessary as a solution to compensate the difference with compliance chart and optimize stent-to-artery ratio (16).

Post-dilatation balloon applied to stents tend to achieve lesser diameter enlargement than indicated by their post dilatation balloon compliance chart. Nevertheless, all stent platforms here could achieve with their largest design a MSA ranging from 22.2mm^2 to 28.4 mm^2 and a MLD ranging from 5.3 mm to 6.0 mm, which can accommodate most left main anatomies.

It can also be observed that stent platforms with only two designs are able to generally expand as much as stents with more designs, indicating that only 2 stent designs does not necessary hinder the stent's overexpansion capabilities.

11. Crown angle

It can be observed that overexpansion of the stents leads to a large discrepancy in crown angles, with increase ranging from 50% up to a 151% increase in crown angles. Large crown angle >150° indicates that the stent crowns are almost completely straightened and the stent is reaching its physical limit. Overexpansion and straightening of crowns is expected to be associated with increased radial force and stiffness. Although increase in radial force is good, an increase in stiffness can reduce the stent durability and get it more prone to fatigue and stent

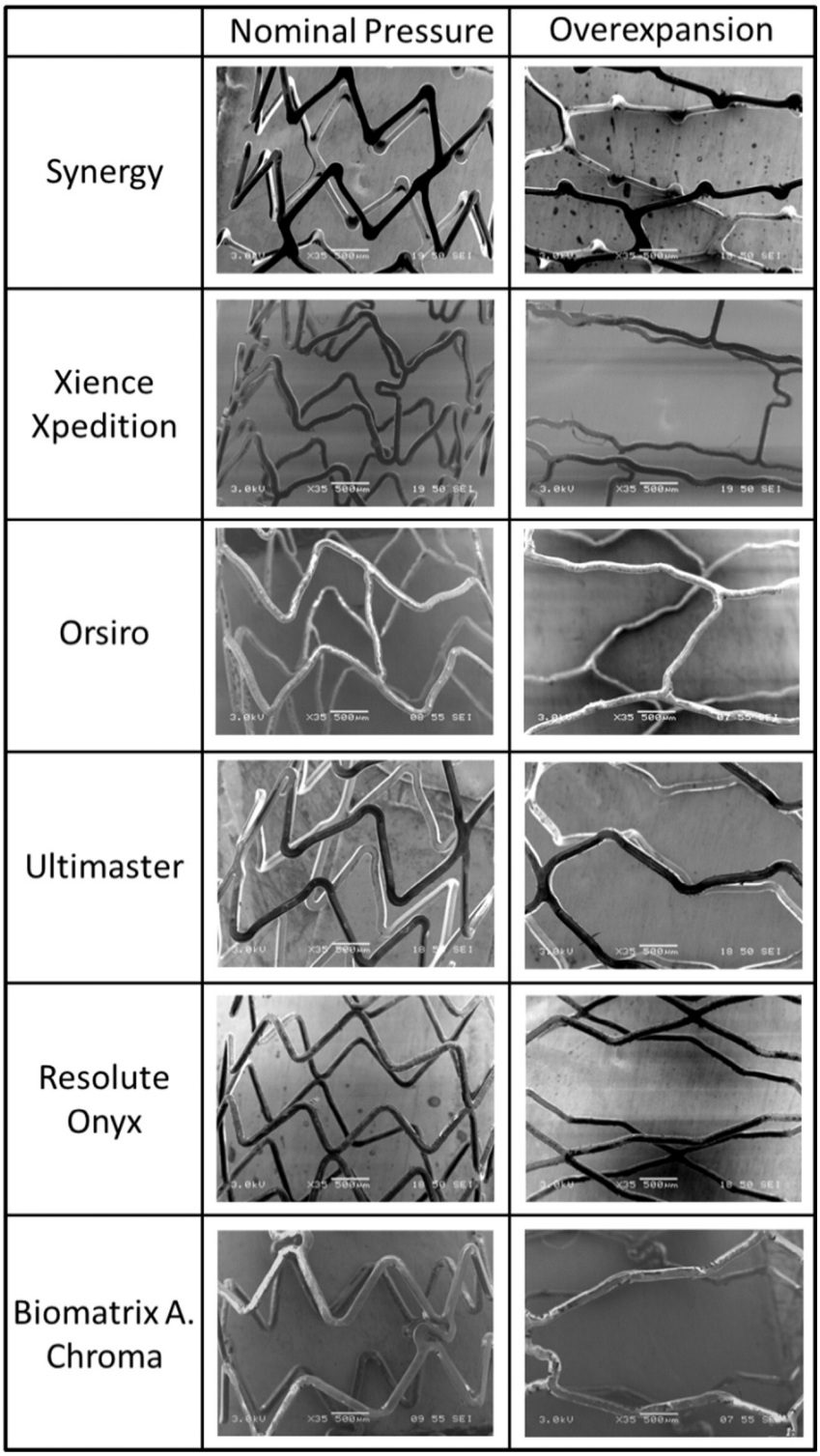


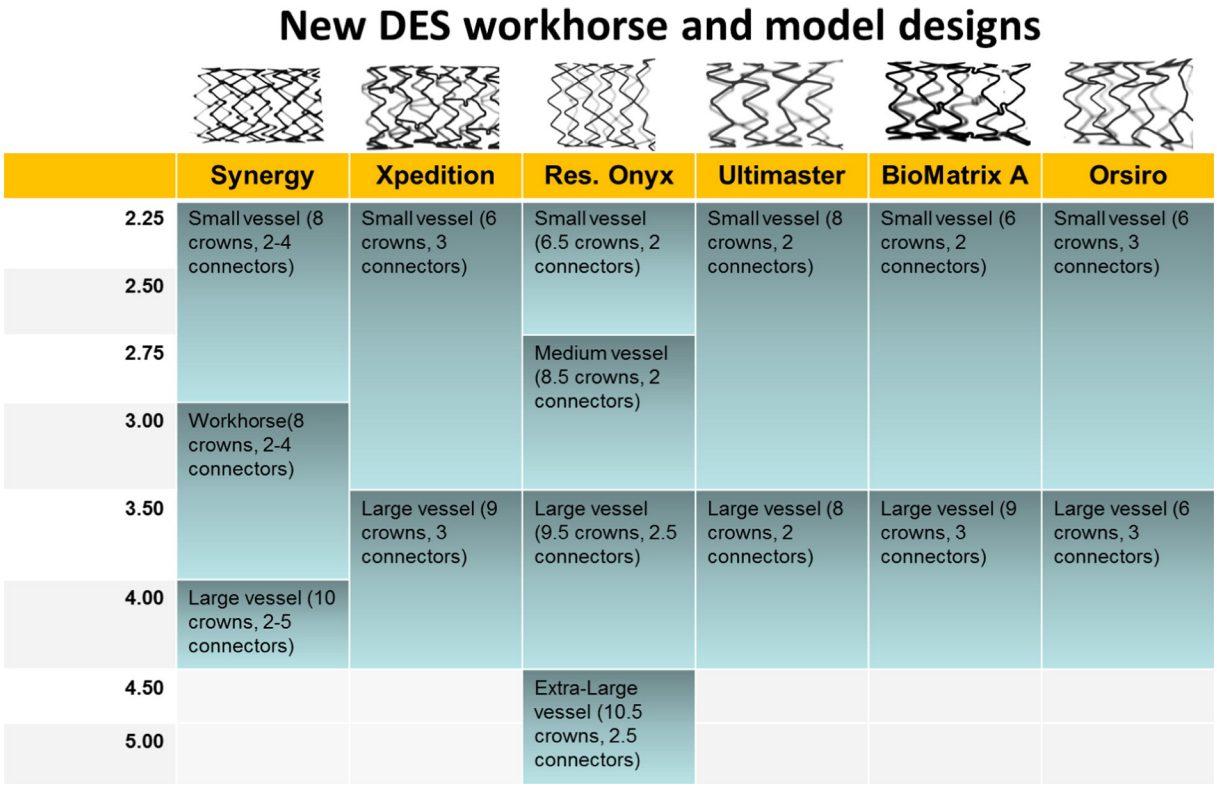
Fig. 5. SEM analysis of DESs after nominal pressure (left) deployment and overexpansion (right): Stents shown in the table are the largest workhorse design for each platform. All stents were first post dilated using a 5 mm NC balloon followed by overexpansion with a 6.0 mm SC balloon. Overexpansion causes visible straightening of the stent struts. Most coating resisted well despite oversizing with only minor cracks on the coating appearing in the crowns when deformation was the most severe.

fracture (2). Recent bench studies have shown the impact of stent designs and connectors on mechanical response, such as longitudinal strength and bending fracture (20,21).

12. Cell opening diameter

Cell opening diameter increase during overexpansion also varies largely depending on stent design: we observed a range up to 164% increase in cell opening diameter. This indicates an increase in cell size during overexpansion and the distance between strut scaffolds, hence increasing the risk of underlying plaque prolapse in between the struts. The increased gap between strut scaffolding can also negatively affect the drug eluting properties of the stent, potentially causing reduction in drug elution in overexpanded regions and chance of neointimal proliferation. A study done previously by Basalus et al. showed how cell area of a partly overexpanded stents varied based on the location

Table 1
DES workhorse and model designs: This table shows the designs of stents for each platform and also the sizes covered for each design. Most DESs only use 2 designs to cover the entire range of diameters, with the exception of *Synergy* and *Resolute Onyx*.



of the cell and the larger cell opening was shown to be at the transition region between the oversized and nominal segment (17). Although the relationship between struts scaffolding and drug distribution per unit area and the onset of restenosis is not known, careful stent selection based on design model is important to minimize stent deformations and risk of prolapse.

13. Drug coating integrity

Damage on the drug coating was not specifically looked at in this study. Overexpansion subjects the stent strut and the coating to extreme forces and deformation (14), increasing the risk of polymer coating damage. Other studies have addressed previously this point (14) and it is important to realize that the drug coating can be affected during severe over-expansion or Kissing Balloon technique. Drug coating damages or detachment of debris may expose patients to potential risks of thrombosis and inflammation with neointimal reactions (22,23). In Fig. 5, scanning electron microscope (SEM) images of each stent design at nominal pressure deployment as well as after overexpansion show that, although some minor coating defects may start to appear at the crowns which undergo the most severe

Table 2
Measured values of MSA and LD from cross-sectional and longitudinal images: The measurements are the minimal lumen diameter within the boundaries of the stent (not including the strut). Values obtained are the average of the measurement from 2 oversized samples for each stent design. Percentage change was calculated using the measurement values obtained using the longitudinal axis of the stent. All 4.0 mm DESs could be expanded to at least 5.3 mm with a 6.0 mm semi-compliant balloon at 14ATM.

Stent	Model design	Largest stent size NP (mm)	Max expansion balloon (mm)	Cross-sectional				Longitudinal		% Increase in LD after overexpansion
				LD		MSA		LD Edge	LD 5 mm	
				Minimum	Average	Average	SD			
Synergy	SV	2.75	5.0	3.6	3.6	11.4	0.4	3.7	3.7	53
	WH	3.5	5.0	4.2	4.2	14.4	0.5	4.1	4.2	57
	LV	4.0	6.0	5.7	5.7	27.5	0.3	5.8	5.8	56
Xience	SV	3.0	5.0	4.0	4.1	13.6	0.4	4.2	4.2	48
	LV	4.0	6.0	5.6	5.6	26.1	1.3	5.6	5.5	67
Orsiro	SV	3.0	5.0	4.0	4.0	13.0	0.2	4.0	4.3	60
	LV	4.0	6.0	5.2	5.3	22.2	0.5	5.3	5.5	58
Ultimaster	SV	3.0	5.0	4.3	4.3	15.1	0.0	4.3	4.4	69
	LV	4.0	6.0	5.8	5.8	27.5	0.3	5.7	5.8	63
Resolute Onyx	SV	2.5	4.0	3.3	3.3	9.1	0.0	3.4	3.6	43
	MV	3.0	5.0	4.3	4.4	15.5	0.1	4.3	4.5	60
	LV	4.0	6.0	5.5	5.6	24.6	0.1	5.5	5.2	39
	XL	5.0	6.0	5.9	6.0	28.4	0.3	6.0	6.0	25
BioMatrixA/Chroma	SV	3.0	5.0	4.1	4.1	14.0	0.1	4.3	4.3	61
	LV	4.0	6.0	5.8	5.9	27.7	0.1	5.9	5.8	78

Table 3
Measured and derived cell opening and crown angle values and percentages: The percentage change in crown angle and cell opening varies based on the design used. Cell opening diameters at the segment of the stent transition from the nominal deployment to the over expanded segment showed the largest cell opening diameters and are noted down as the maximal transitional cell opening. The cell opening and crown angle values are obtained from the average of 6 measurements, 3 different locations per sample and 2 samples per stent design.

Stent	Model design	Largest stent size NP (mm)	Max expansion balloon (mm)	Crown angle (°)			Cell opening (mm)			
				NP	OE	% Increase	NP	OE	% Increase	Maximal transition OE
Synergy	SV	2.75	5.0	82	167	103	0.6	1.5	150	1.7
	WH	3.5	5.0	74	147	98	0.8	1.8	131	2.0
	LV	4.0	6.0	80	157	97	0.8	1.9	145	2.2
Xience	SV	3.0	5.0	79	156	97	1.1	1.6	48	1.8
	LV	4.0	6.0	74	154	108	0.9	1.7	83	1.9
Orsiro	SV	3.0	5.0	82	151	85	0.6	1.5	164	1.7
	LV	4.0	6.0	95	157	65	0.8	2.0	145	2.2
Ultimaster	SV	3.0	5.0	68	124	83	0.7	1.6	119	2.1
	LV	4.0	6.0	68	131	93	1.0	2.2	123	3.0
Resolute Onyx	SV	2.5	4.0	81	128	59	0.9	1.7	90	1.8
	MV	3.0	5.0	72	126	76	0.9	1.8	107	2.1
	LV	4.0	6.0	82	158	92	0.9	1.8	104	2.1
	XL	5.0	6.0	81	122	50	0.9	1.7	89	1.8
BioMatrixA/Chroma	SV	3.0	5.0	68	155	129	1.1	1.8	70	1.9
	LV	4.0	6.0	63	159	151	1.0	2.5	147	2.6

deformation, stent coating resisted overall well for all the DESs during oversizing.

14. Radial strength

As stent crowns straighten, the resulting radial force of the stent is also expected to increase. Although not specifically looked at in this study, overexpansion also increases stent stiffness due to the straightening of the crown close to the stent physical limit (2,24). This may increase risk of strut fracture due to metal fatigue on the stent. Mechanical response and durability data on stents overexpanded close to maximal expansion capacity are still lacking and need to be evaluated further.

15. Limitations of study

- Measurements obtained from this study should be carefully interpreted as the stents were deployed *in vitro* without the presence of a constraining arterial wall to limit the expansion of the stent. Hence, the results obtain are only an approximation of the actual *in vivo* behaviour of the stent-artery response during overstretching (25). Also, the hoop force the balloon has to overcome to induce further stent deformation would be much higher *in vivo* due to the presence of stiff fibrotic plaque.
- In some design, increasing the diameter of the balloon used may further straighten the struts and further expand the stents. The largest maximal balloon diameter used in this study was 6.0 mm and the dilatation pressure was limited to the Rated Burst Pressure (14 ATM), equivalent to a maximal balloon diameter of 6.46 mm. The Inner MLD achieved on the stent large designs was inferior to this balloon size by at least 0.5 mm.
- Both the radial strength and drug kinetics of stents were not sufficiently investigated in this study. As such, the key information on the importance of stent oversizing alone does not allow for a complete assessment of which stent is preferable.

16. Conclusion

Knowledge of the cut-off diameters between different stent models has been previously shown to help in selecting the most suitable stent size and hence help in the treatment of large bifurcation and left main PCI. Careful selection of size according to contemporary DES model designs may help to avoid implanting stent sizes with too limited expansion capacity which could result in malapposition and severe overstretching of the stent.

Conflict of interest

The authors report no relationships that could be construed as a conflict of interest.

Acknowledgements

This study was independently initiated and conducted by the authors. No industry sponsor was received for the study and only the test samples were provided in kinds by the manufacturers for the experiments. The authors would like to thank the manufacturers for accepting to provide test samples for this study.

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