CHAPTER 71

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Stent Design: What You Must Know?

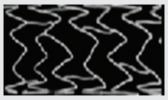
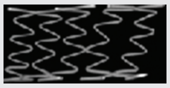
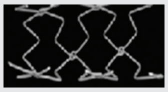
Advances and refinements in stent technology over past three decades has significantly revolutionized percutaneous coronary interventions treatment, now stents are successfully deployed and used in more and more challenging and complex coronary anatomy with good long-term results. Therefore in this changing scientific scenario, knowledge of stents design with tips and tricks of positioning and deployment of appropriate design stents in given anatomy is of great value and comes handy for successful and appropriated use of stents. It is pertinent to mention here that stent design consists of platform (metal and architecture), drug and polymer.

Considerable advances have been made in platform, drug and polymer to inhibit restenosis, late and very late stent thrombosis while promoting optimal endothelialization and reducing dependence on long term dual antiplatelet therapy. Polymer is changed from durable to biodegradable polymer or even polymer free drug eluting stent (DES) is available to reduce hypersensitivity and inflammation to prevent stent thrombosis (ST) observed in first generation DES. Drug dose, kinetics and drug-coating pattern are also altered on new generation DES to combat negative remodeling and to curb thrombotic nidus formation. The design has been up graded to incorporate thinner struts and to do this, stainless steel platform has been replaced by suitable metal alloy platform **(Table 1)**.

By reducing the size of the struts and by altering the architecture, the stress and strain on the vessel is reduced considerably which in turn reduces the restenosis and stent thrombosis by reducing the quantum of injury during the deployment. It is pertinent to state here that in stent restenosis rate (ISR) is directly proportional to the quantum of injury during procedure. Metallic stents are now non-ferromagnetic which allows stents to become MRI compatible. In addition platform and drugs have been customized to treat specific patient profiles such as small vessel, bifurcation lesions and diabetic subsets for example zotarolimus-coated DES is US Food and Drug Administration (USFDA) approved for diabetic subsets and multiple DES of 2 mm or 2.25 mm sizes are also approved for deploying in smaller vessels. Now non-metallic bioresorbable vascular scaffold (BVS) technology platform has been developed without compromising radial strength and scaffolding characteristics.

Ten types and varieties of technically refined absorbable stents are expected to enter the market in next two years with thinner struts, longer lengths, bigger diameters and improved platform to suit their use in more challenging and complex anatomy. For example, currently available BVS has 156 micron struts (150 micron struts plus 6 micron of drug coating) will be reduced close to 100 micron strut size and will be available for commercial use in next 2 years after trials. In my opinion, absorbable or dissolvable stents may completely replace metallic DES in time to come as BVS preserve vasomotion which is vital for propelling the blood in the artery, whereas vasomotion is significantly affected with metallic DES. Secondly by being absorbed, it eliminates permanent metal cage and also prevents chance of metal fatigue observed with metallic DES after many years. Third late luminal gain in BVS is distinct advantage over late luminal loss in DES. It is well known that metal fatigue in metallic DES may clinically present as acute coronary syndrome (ACS) or stable coronary artery disease (CAD) due to stent fracture or loss of scaffolding characteristics. It has been demonstrated by in vitro experiment that exposing the metal stent to normal BP over 10 years may lead to metal fatigue but *in vivo* this duration may vary due to variation in BP and endothelialization cover,

Table 1 Drug-eluting stent (DES) Design Characteristics

Architecture	*Name*	*Alloy*	*Strut thickness (μm)*	*Drug*	*Polymer*	*Number of*		*Over Expansion (mm)*	*Balloon marker to stent gap (mm)*	
						Crowns	Connectors		Proximal	Distal
	Orsiro	CoCr	60	Sirolimus (1.4 ug/ mm^2)	PLLA bioabsorbable	7	3	NA	NA	NA
	Promus Element	PtCr	81	Everolimus (1.0 ug/ mm^2)	Fluorinated polymer	8	2	4.5	0.40	0.40
	Xience	CoCr(L-605)	81	Everolimus (1.0 ug/ mm^2)	Fluorinated polymer	6	3	4.4	0.0	0.0
	Taxus Liberte	316L SS	96	Paclitaxel (1.0 ug/ mm^2)	Translute	9	3	4.7	NA	NA
	Integrity	CoCr(MP-35-N)	91	Zotarolimus (1.6 ug/ mm^2)	Biolinx (PC Coating)	10	2	5.0	0.48	0.48
	Biomatrix Flex	316L SS	120	Biolimus (15.6 ug/ mm^2)	PLA bioabsorbable	6	2	4.4	NA	NA
	Cypher Select	316L SS	140	Sirolimus (1.4 ug/ mm^2)	PEVA/PBMA	6	6	4.7	NA	NA

hence average life of metallic stent is difficult to predict that is why it is not being so much emphasized in clinical practice. However, metal fatigue is surely an issue with metallic DES.[1-6]

In ostial lesion deploying a stent is always a challenge particularly to prevent geographic miss at the ostium so that stent does not either hang into the main vessel or get deployed behind the ostium in the proximal segment of the vessel which may pose problem in long-term results. Therefore to deploy the stent properly at the ostium, knowledge of gap between the balloon marker and the stent proximal edge **(Table 1)** is very vital in metallic DES even when newer technique of deploying stent in the ostial lesion is practiced and this gap technically varies from stent to stent. It is necessary to select an optimal angiographic view and memorize the distance between the proximal marker of the balloon and the proximal extremity of the stent. The stent boost may preferably be used for clearly identifying the balloon marker and proximal end of stent for accurate stent positioning at the ostium. Sometimes stents ping pong and pose significant challenge in accurately deploying the stent at the ostium which can be overcome by deep breathholding maneuver and another important trick is to perform sub-optimal predilatation at the lesion just enough to allow smooth passage of stent.

At this juncture, it is pertinent to discuss two unique techniques of positioning metallic DES into ostium. Both these techniques can be used in Medina 001 or 010 of bifurcation lesion.

Tail-wire (Szabo) technique: This very unique technique has been used to deploy metallic DES accurately at the ostium to avoid geographic miss. In this technique, two wires are used, one goes to main branch (MB) and another goes to side branch (SB). The hard end of the SB wire is then passed through the proximal most strut or cell of the stent by inflating the stent outside on MB wire at 1 or 2 Bar atmosphere which by dictum will open up the proximal most strut first and allow the SB wire to pass through it easily and then slowly the stent is advanced on both wires right up to the MB ostium till you feel tactile resistance and that is when the position of stent is studied in optimal angiographic view under stent boost. The stent is first deployed at a nominal pressure and then SB wire is pulled out while keeping the deflated stent balloon in the same position, this step is meant to prevent tight jailing of SB wire; then stent is deployed at a higher pressure with the same stent balloon to completely embed the stent to the vessel wall. With this technique, success rate of ostial deployment is 97.6% as confirmed by IVUS imaging and stent malposition rate is much lower at 6.40% as compared to 41% when stent is positioned in the ostium by angiographic imaging and the incomplete stent coverage of the plaque is 0% with Szabo as compared to 7.7% by angiographic ostial positioning.[7] It is important to mention here that technically all stents have an invisible colorless fine coating which acts like a tight sheath to adhere the stent on the balloon and that invisible sheath technology allows the stent to first open from the proximal end only and one should not fear of dislodging the stent as stent is still adhered to the balloon by colorless coating in middle and distal part of the stent, although initially few stents have been reported to have dislodged while doing this technique.

Backstop technique: This technique consists of placement of 2 wires, one in SB and second in MB. The stent is then positioned carefully at stenotic site at the bifurcation by angiographic imaging and stent boost. Plain balloon is passed on the SB wire and positioned half in the SB and half in the main vessel. This plain balloon is undersized so as not to disrupt the intimal wall. Plain balloon and stent is simultaneously inflated (balloon at low pressure and stent at nominal pressure) and some operators prefer to inflate the balloon first and slightly pull the uninflated stent until some resistance is felt and then inflating the stent. With this technique, snowploughing the plaque into the ostium of the clean vessel is fully prevented and also helps in accurately positioning the stent in the ostium.[8]

Whereas in bioresorbable vascular scaffold (BVS), the marker is on the stent and stent edges proximally and distally are minimally ahead of the marker so in turn the stent extends beyond the stent markers at both ends (proximally 1.1 mm and distally 0.7 mm). Hence geographic miss at the ostium is less likely with the absorb stent as some part of the stent may overhang in the main vessel beyond the ostium which will get absorbed by being in contact with fluid. It is pertinent to mention that BVS is absorbed by being in contact with fluid or water. Deploying an absorb stent is technically different from metallic DES as BVS expands during deployment by the inflation pressure on the balloon and also by temperature of the blood that is why deployment has to be slow at the rate of 2 Bars every 5 seconds so that the stent gets enough time to get warm by being in contact with the blood and slowly gets deployed well to the vessel wall over 30–60 seconds.[9-11] BVS is non-radiopaque stent, so positioning BVS stent in the ostium is achieved by positioning the stent marker at the ostium in proper angiographic view and under stent boost. There is minimal gap between balloon and stent markers in BVS. Most markers on balloon and stent is currently made of platinum-iridium alloy.

Distal gap between the marker and stent is important while overlapping the stent in longer lesions and it is particularly important in BVS as it needs to be deployed edge to edge as sizes of the strut in current absorb stent is almost 160 micron so overlapping the stent may produce default stenosis at the site of overlap which may unfavorably alter the blood rheology and may induce stent thrombosis. While positioning BVS edge to edge, balloon marker of proximal stent should be just adjacent to distal stent marker in suitable angiographic view under stent boost. Recently, Absorb III trial results reported higher stent thrombosis rate particularly in 2.5 mm diameter non-overlapping BVS.[12] This higher ST rate in smaller BVS is supposed to be due to change in blood rheology because of high strut thickness. To overcome this issue in 2.5 mm BVS[13-15,] it is advisable to post-dilate it with 0.25 mm oversize NC balloon to minimally reduce strut and stent thickness to prevent ST.[12]

It is pertinent to note here that ST in BVS has higher mortality as compared to metallic DES thrombosis hence it is all the more vital to properly deploy all stents. If cine view shows minimal waist on BVS stent balloon or sometimes one may not be sure about under expansion of BVS as it being a non-radiopaque stent therefore imaging by OCT is better than stent boost for diagnosing under deployed BVS. BVS struts are visible as small boxes on OCT imaging whereas DES struts appears as bright short horizontal lines. Stent to artery size ratio recommended for DES and BVS use is 1:1. Initially, 16 bars atmosphere was recommended as maximum pressure for BVS deployment. However now with experience, one can go up to 26 Bars pressure with 1:1 size NC balloon to fully expand BVS and such high pressures have been found to be tolerated well on BVS as it does not seem to cause strut or stent fractures as depicted by OCT imaging time and again.[12] It is pertinent to mention here that more than 30% of ISR is due to under expanded stent therefore fully expanding the stent is crucial for optimal long-term results. Preferable DAPT regimen for BVS is aspirin 75 mg OD and ticagrelor 90 mg BD to prevent stent thrombosis. Whereas in DES, any combination of DAPT regimen may be reasonable except DES in complex PCI where aspirin and ticagrelor combination may be preferable to prevent ST. Currently, ACC/AHA guidelines recommend DAPT regimen duration as six months for stable CAD whereas for ACS DAPT is recommended 1 year[16] and switching over to another theinopyridine derivative mandates loading dose.

Stent in bifurcation lesions are deployed either by provisional or by elective double-stenting (EDS) techniques and technically stent to be used for bifurcation lesions should fulfil following criteria:

- Stent should provide optimal apposition at proximal, distal and bifurcation site
- Stent should have ability to over expand to fit proximal and distal vessel sizes
- Side-branch access should be large enough to promote entry of stent and balloon into side branch (**Table 2** is depicting perimeter sizes of three internationally used DES). It is needless to mention here that open cell design stents are mandated for bifurcation lesion. Selection of stent diameter size is based on the distal MB size, as the larger diameter stent may significantly increase the risk of SB occlusion due to carina shift, hence optimizing stent diameter size is extremely vital in bifurcation lesion.

Table 2 Stent cell size after expansion

3.0 mm Stent	*Diameter (mm)*
Resolute Integrity DES	3.84
Xience Prime DES	3.80
Promus Element DES	3.48

Now multiple variety of dedicated bifurcation stents are also available **(Table 3)**, however, currently these are not popular in practice as about 80% bifurcation lesions are managed by provisional stenting.

Understanding the role of Proximal Optimisation Technique ("POT") is crucial in bifurcation lesion at this juncture. It is pertinent here to have knowledge of expansion

Table 3 Main characteristics of Dedicated Bifurcation stents

Stents type	*Manu-facturer*	*GC*	*Mechanism of stent expansion*	*Stent material*	*SDS*	*Drug-eluted*	*SB protection*	*Ostial SB coverage*	*Comments*
Sidekick™	Y-Med	5F	Balloon-expandable	Cobalt Chromium	Single rapid exchange system	–	+	+/–	Partial coverage of SB ostium; Potential SB gap when placing second stent
Frontier™	Guidant/ Abbott	7F	Balloon-expandable	Stainless Steel	Double balloon, single wire tracking, dual lumen tip, MB rapid exchange and SB over-the-wire	–	+	+/–	Partial coverage of SB ostium; Potential SB gap when placing second stent
Invatec Twin-Rail™	Invatec	6F	Balloon-expandable	Stainless Steel	Double balloon, dual rapid exchange system	–	+	+/–	Tracks over 2 wires; Partial coverage of SB ostium; Potential SB gap when placing second stent; No DES under development
Nile CroCo™	Minvasys	6F	Balloon-expandable	Cobalt Chromium	Double balloon, dual rapid exchange system, 2 independent catheters	–	+	+/–	Tracks over 2 wires; Partial coverage of SB ostium; Potential SB gap when placing second stent; No DES under development
SLK view™	Advanced Stent Technology	8F	Balloon-expandable	Stainless Steel	Single balloon, dual over-the-wire system	–	+	–	No coverage of SB ostium, No DES under development
Stentys™	Stentys	7F	Self-expandable	Nitinol	Single balloon single rapid exchange system	Paclitaxel-PESU polymer	–	+/–	Partial coverage of SB ostium; Potential SB gap when placing second stent
Petal™	Boston Scientific	7F	Balloon-expandable	Platinum Chromium	Double balloon dual rapid exchange system	Paclitaxel-Translute polymer	+	+	Tracks over 2 wires
Antares™	Trireme Medical Inc	6F	Balloon-expandable	Stainless Steel	Single balloon, single rapid exchange system	–	+	+	No DES under development
Sideguard™	Capella	6F	Self-expandable	Nitinol	Single balloon, single rapid exchange system	–	N/A	++	Stenting of both branches mandatory
Tryton™	Tryton Meical	6F	Balloon-expandable	Cobalt Chromium	Single balloon, single rapid, exchange system	–	N/A	++	Stenting of both branches mandatory; No DES under development
Axxess™	Devax	7F	Self-expandable	Nitinol	Single wire rapid exchange system	Biolimum A9- PLA polymer	+	–	Requires 3 stents for complete coverage

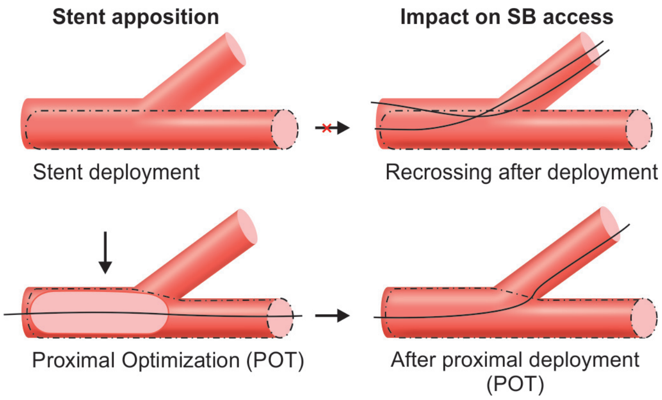


Fig. 1 Importance of POT

capability of all type stents beyond their stated size while performing POT **(Table 1)**. The selection of the stent diameter size is based on the distal MB diameter beyond SB and understandably proximal MB is bound to be larger in diameter that is where POT is recommended for well apposition.

Of the stent to proximal MB wall as doing POT here will prevent the wire going underneath the stent while rewiring SB and facilitate re-entry of wire in SB.[17,18] Selection of NC balloon diameter for POT is based on the formula: MB distal lumen diameter + SB lumen diameter × 2/3. Optimal balloon diameter size is important to well appose stent to artery wall. POT balloon length also be short enough so that the distal end of balloon ends at the origin of the SB.

POT should be done while keeping the SB wire jailed as the jailed SB wire left in place helps as a marker to re-cross the SB and in addition jailed wire also favorably modifies the angle between the two branches and keeps the SB open **(Fig. 1)**. After POT two wires are exchanged so that MB wire goes to SB and vice versa. At times, wiring the SB may be technically difficult for which new hydrophilic wire will be required or even microcatheter may help to overcome the technical issues. After re-crossing the SB and MB wires, final kissing balloon inflation (FKI) is performed using shorter NC balloons. FKI is proposed to correct the MB stent distortion and expansion and provide better scaffolding of the SB ostium and facilitate future access to the SB. Another technique recently proposed is of sequential balloon inflations beginning with the SB instead of simultaneous inflation in FKI in order to achieve better SB opening and to do proper scaffolding of MB/SB. In the latter technique, the SB is inflated at 12 Bars first, and then MB at 12 Bars while deflating the SB balloon at 4 Bar so that elliptical stent deformation is reduced and the SB access is optimized for future procedures. The elliptical stent deformation is also associated with higher rate of stent thrombosis.[17,18]

At times, stent positioning may be a challenging task due to presence of calcium or due to tortuosity of the vessel. One should avoid force in positioning stent as it may damage distal struts or design architecture of stent which may pose problem in properly deploying stent, consequently may lead to acute or subacute stent closure or ISR. Secondly, forcing the stent can also cause major dissection of vessel wall, slow flow or no flow and acute thrombosis during procedure consequent hypotension and may lead to catastrophic event on cath table.

Third, stent dislodgement may be possible complication of forcing to position the stent. Hence, to overcome this difficulty of positioning stent, best step would be to re-dilate the lesion at higher pressures either by 1:1 NC balloon or cutting balloon or angiosculpt balloon to properly prepare the lesion for smooth positioning of stent. Advantage with angiosculpt balloon is that it does not lead to perforation at high pressures whereas cutting balloon is known to cause perforation at high pressures. If the calcium is circumferential, then debulking with rotational atherectomy may help in successfully positioning the stent. Alternatively, multiple short stents may be used to cover the diseased segment in case single long stent is unable to cross the diseased segment or else, buddy wire technique may be used particularly in tortuous vessel anatomy to position the stent; in this technique, two wires are used, the stent is on the extra support wire and while pushing the stent, the buddy wire is slightly pulled out simultaneously to successfully position the stent in challenging anatomy. Newer grandslam wire may also be useful in these challenging circumstances while performing buddy wire technique.

Longitudinal stent deformation (LSD) is a new complication reported after thinner struts DES came in vogue and LSD is notoriously known to occur due to guide catheter extension or sucking in of guide catheter while doing ostial lesion, LMCA lesion or proximal RCA lesion or proximal LAD lesion, so care must be taken not to allow guide extension into the stent. It is likely to occur while post dilatation balloon is being withdrawn. LSD can occur secondary to device like IVUS catheter or balloon catheter and in device induced LSD, re-entering the deformed stent is more difficult. The device induced seem to occur more with the promus element stent while guide catheter extension induced occurs across all types of stents.[18-21]

Longitudinal stent deformation (LSD) seem to occur with all varieties of stents though tendency is more in longitudinally weaker stents. **Figure 2** depicts longitudinal strength of multiple variety of stents. LSD is also known to occur with BVS though the exact incidence is not reported in literature at the moment but few cases are reported of LSD in BVS **(Fig. 3)**. LSD in BVS is diagnosed either by displacement of the stent marker recorded by stent boost or OCT imaging may be preferable as BVS is a non-radiopaque stent. Whereas LSD is easily in BVS is diagnosed either by displacement of the stent marker recorded by stent boost or OCT imaging may be preferable as BVS is a non-radiopaque stent. LSD is a major complication and therefore should be treated on the table itself during the procedure by sequential balloon dilatation starting from smaller to bigger balloon diameter.

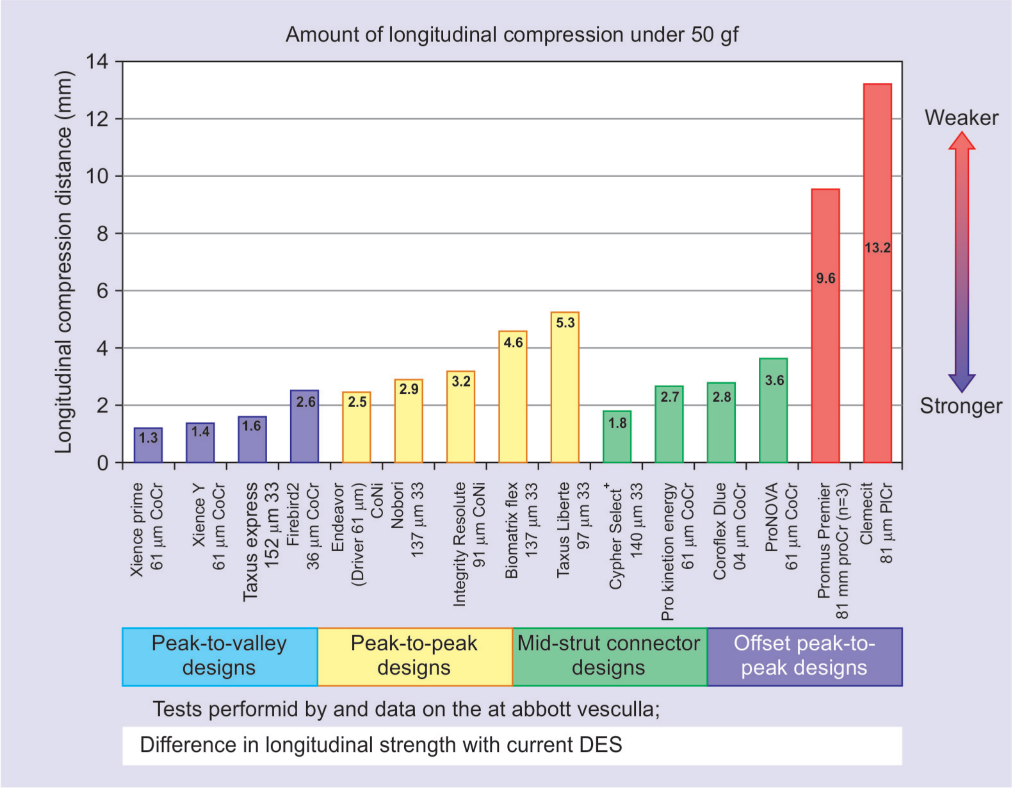
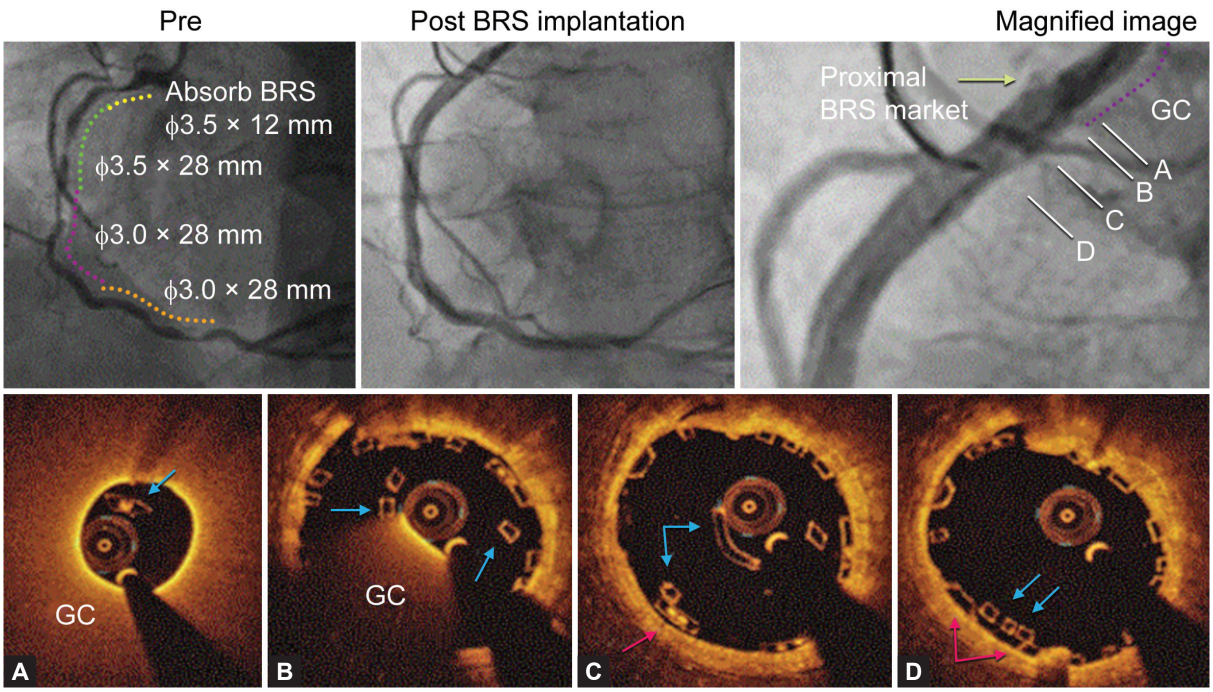


Fig. 2 Longitudinal strength of all varieties of stents



Figs 3A to D Longitudinal stent deformation (LSD) in bioresorbable vascular scaffold (BVS) (A) Disrupted bioresorbable scaffold (BRS) strut is visible within the guiding catheter (GC); (B and C) Disrupted BRS struts (ble arrows) are surrounding the GC; (D) Disrupted BRS struts are seen overlapping struts that are structurally intact (red arrows) and well apposed to the vessel wall. From these findings, the proximal edge of the BRS appeared to be caught within the GC and then subsequently abutted distally

Abbreviation: OCT, otpical coherence tomography.

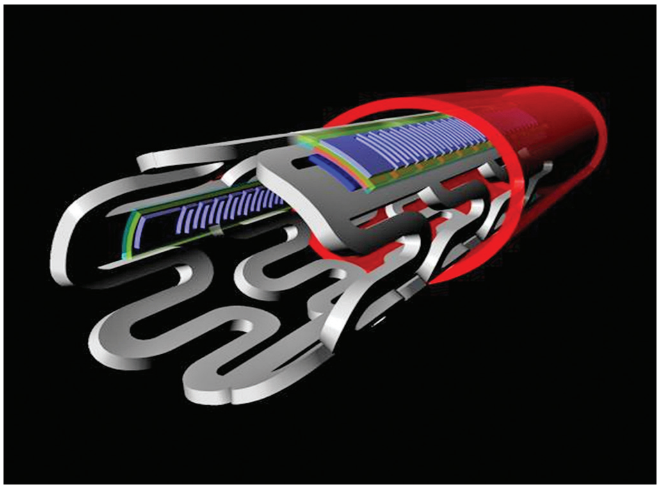


Fig. 4 Bioresorbable electronic scaffold (BES)

In case, the balloon inflation is unable to correct the LSD, then a new stent may be deployed overlapping LSD segment of the previous stent.[22]

Despite multiple progressive advancements in stent technology, hunt for ideal stent is still on. In my opinion ideal stent would be one which gets dissolved completely in 6 months while restoring vasomotion fully, not requiring any further antiplatelet regimen and can be used in any complex anatomy with great deliverability and scaffolding characteristics. But soon realized that my opinion is far away from future stent technology when I happened to come across this incredible design called Electronics Embedded Bioresorbable Stent and named as 'Bioresorbable Electronic Stent (BES)'. A Korean led team recently published their research on the first device of its kind, showing proof of concept in the American Chemical Society Journal from ACS Nano **(Fig. 4)**.[23] This was presented in last TCT and ACC meetings in recent future technology session. Electronics embedded are using nano technology in magnesium scaffold which can monitor blood flow and temperature, etc. BES will also be completely absorbed including electronics. Currently, BES is featuring at concept stage.

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