Drug Coated Balloon Technology within Coronary Angioplasty

BASIC TRAINING FOR CATH LAB STAFF

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CONTENTS

EVOLUTION IN ANGIOPLASTY

It is important to see where technologies have come from in order to truly understand them.

1929 – First Cardiac Catheterisation diagnostic procedure

1956 – Cardiac Catheterisation awarded Noble Prize

1977 – First ever Plain Old Balloon Angioplasty (POBA) treatment performed

1986 – First Coronary Bare Metal Stent (BMS) implanted in a human

1987 – Palmaz-Schatz stent designed which was expanded using a balloon

1994 – BENESTENT & STRESS RCTs proved superiority of BMS over POBA

1996 – Introduction of Dual Antiplatelet Therapy (DAPT) to prevent stent thrombosis

2002 – First generation Drug Eluting Stent (DES) released to market

2006 – Meta-analysis linked DES to an increase in late stent thrombosis & death[1,2]

2007/2008 – Second Generation DES designed & released to market

2009 – SeQuent® Please DCB launched to market

2010 – NICE recommends SeQuent® Please for in-stent restenosis[6]

2015 – Meta-analysis confirms safety & efficacy of second generation DES[3]

2015 – Launch of second generation SeQuent® Please NEO DCB

2018 – SeQuent® Please NEO found to be non-inferior to DES in SVD[4]

EVOLUTION IN ANGIOPLASTY

PCI is one of the most common medical procedures worldwide. PCI celebrated its 40th year anniversary in 2017 and since 1977, there has been a significant improvement in treatment technologies.

Plain Old Balloon Angioplasty (POBA)

Although revolutionary in 1977, POBA produced unpredictable procedural outcomes due to vessel dissection, vessel recoil and high restenosis rates. The patient would often require repeat dilation or bypass surgery.

Bare Metal Stents (BMS)

BMS produced more stable results with lower restenosis rates. However, challenges with this technology included early stent thrombosis and neointimal hyperplasia – proliferation of smooth muscle cells within the intima layer of the artery wall leading to a decrease in lumen diameter and vessel re-narrowing.

Drug Eluting Stents (DES)

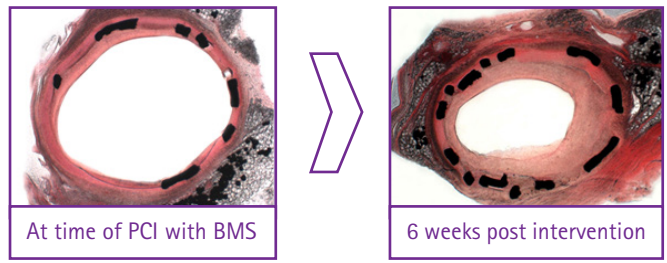
The introduction of DES significantly improved patient outcomes by delivering an anti-proliferative agent to the vessel wall. This lowered the rate of in-stent restenosis (ISR) and allowed the use of PCI in more advanced and complex disease. Whilst first generation DES were correlated to an increase in late stent thrombosis and patient death, second generation DES have been proven to be safe and effective[3].

CHALLENGES WITH DRUG ELUTING STENTS (DES)

IN-STENT RESTENOSIS (ISR)

The re-narrowing of a blood vessel which was previously treated with a stent during PCI leading to restricted blood flow.

ISR remains a challenge in the interventional cardiology community, on average ISR occurs in 5% of all PCI cases[5].

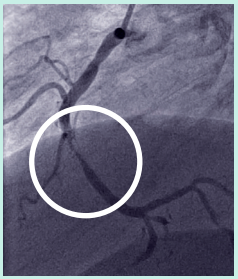


At time of PCI with BMS

6 weeks post intervention

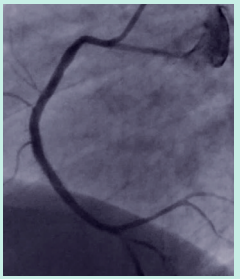
The European Society of Cardiology have given DCBs a Class 1A recommendation for ISR. Such recommendations are based around the vast amount of supporting clinical data in randomised controlled trials[7].

ISR DCB-ONLY CASE STUDY



Pre-treatment

Post-treatment



4-month follow-up

Patient: Male, 55 years

Indication: ISR of BMS (3.5 x 15 mm) implanted 2 years previously

Procedure:

LESION PREPARATION

Pre-dilation PTCA balloon (3.5 x 15 mm)

LESION THERAPY

DCB-only SeQuent® Please
(3.5 x 20 mm) proximal lesion

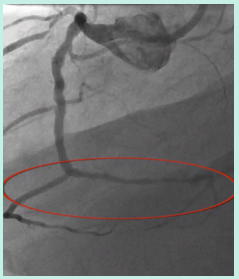
DCB-only SeQuent® Please
(3.5 x 15 mm) distal lesion

Post-treatment: No dissection proximal or distal to the BMS, no residual stenosis present

Follow-up: A very successful result without the need for additional metal within the artery

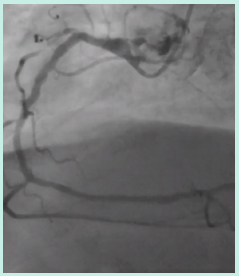
Full case studies available on request.

SMALL VESSEL DISEASE DCB-ONLY CASE STUDY



Pre-treatment

Post-treatment



5-month follow-up

Patient: Male, 74 years

Pre-tratment: Long stenosis of distal right coronary artery

Procedure:

LESION PREPARATION

Pre-dilation PTCA balloon (2.5 x 20 mm)
Two inflations, distal and proximal of posterior descending

LESION THERAPY

DCB-Only SeQuent® Please (2.5 x 20 mm x 2) distal and posterior descending

Post-treatment: No relevant stenosis or dissections present, good TIMI flow

Follow-up: No stenosis after 5 months and a very acceptable result using the DCB-only approach

Full case studies available on request.

BIFURCATIONS DCB-ONLY CASE STUDY


Pre-treatment


Post-treatment


4-month follow-up

Patient: Male, 54 years

Pre-treatment: Stenosis of mid circumflex artery (CX) and its posterolateral branch (PL-CX)

Procedure:

LESION PREPARATION

Pre-dilation PTCA Balloon (2.5 x 20 mm)

LESION THERAPY

DCB-Only SeQuent® Please
(3.0 x 15 mm) of PL-CX
(3.0 x 20 mm) of CX

Post-treatment: No residual stenosis present and good TIMI flow

Follow-up: A successful result without the need for any metal work within the artery

Full case studies available on request.

DCB-ONLY APPROACH

GO IMPLANT FREE

The DCB-only approach is the use of a DCB in place of a stent for a primary coronary intervention and therefore is the concept of 'going implant free' i.e. leaving no metal work behind within the artery.

ADVANTAGES

Avoidance of stent related complications e.g. ISR or stent thrombosis

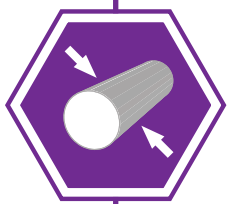
DAPT can be reduced to one month – important for HBR patients or those requiring surgery shortly after intervention[8,9,10]

Enables late lumen enlargement of the target vessel and therefore positive remodelling[8]

WHAT IS LATE LUMEN ENLARGEMENT?

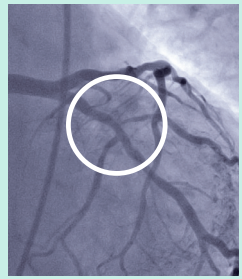
Following treatment using the DCB-only approach, the target vessel lumen diameter can in fact increase in size over time. This is because there is nothing implanted or left behind in the artery, allowing natural vasomotion to continue. Further, the vessel is not restricted in terms of diameter as it is with a stent.

Once a stent is implanted into the vessel, the vessel diameter can never increase, it is restricted by the metal stent struts and therefore can only ever decrease in size. Using a DCB-only approach removes this restriction, as no metal implant is left in the artery. Natural vasomotion supports positive remodelling and therefore late lumen enlargement can occur overtime[8].



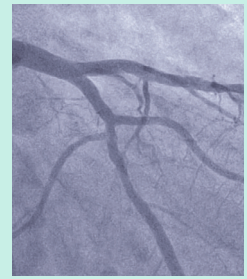
For a clinical paper relating to late lumen enlargement, please refer to reference 1.

WHAT IS LATE LUMEN ENLARGEMENT?



Pre-treatment

Post-treatment



4-month follow-up

Patient: Female, 67 years

Pre-treatment: De novo stenosis of obtuse marginal branch

Procedure:

LESION PREPARATION

Pre-dilation PTCA balloon (2.5 x 15 mm)

LESION THERAPY

DCB-Only SeQuent® Please (2.5 x 20 mm)

Post-treatment: Residual stenosis of <30%, slightly hazy in dilated stenosis but good TIMI flow

Follow-up: Perfect result without any restenosis demonstrating late lumen gain over time

Full case studies available on request.

DCB-ONLY APPROACH CONSENSUS GUIDELINES[9]

LESION PREPARATION

Pre-dilation with

PTCA Balloon | Non-Compliant Balloon | Scoring Balloon

Ratio balloon-vessel-diameter 1.0 - 1.0, inflation pressure > nominal

Acceptable angiographic result: No dissection or only type A or B; TIMI III; residual stenosis ≤ 30 %

DCB-only with SeQuent® Please NEO

DAPT

DCB-only: 1 month

BMS-ISR: 1 month

DES-ISR: Duration defined by DES but at least 1 month

Unacceptable angiographic result: Dissection type C – F; TIMI < III; residual stenosis > 30 %

Stenting

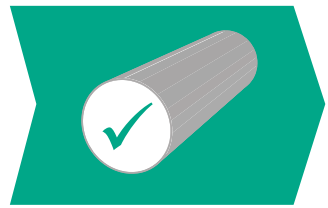
DES implantation Coroflex® ISAR NEO

DAPT according to current guideline

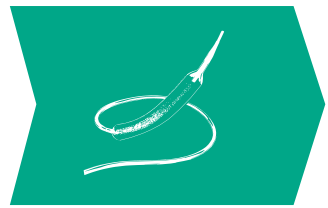
DCB-ONLY APPROACH CONSENSUS GUIDELINES

In comparison to stent implantation, the DCB-only strategy may take longer as adequate lesion preparation must be done gently and with patience. However, the patient can go home without any metalwork in their arteries and therefore has no risk of stent related complications which may require a second intervention.

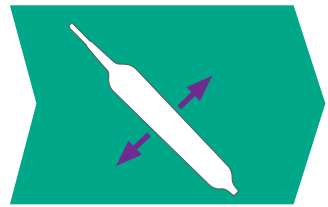
KEY POINTS:



Adequate lesion preparation is mandatory when using the DCB-only approach



The DCB is solely used as a drug delivery system

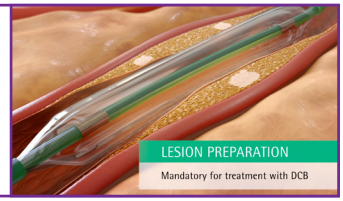


The DCB can be inflated again and used as a standard PTCA balloon if required

DCB-ONLY APPROACH
THE ANGIOPLASTY PROCESS

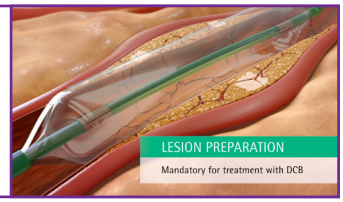
STEP ONE

Mandatory lesion preparation using a standard PTCA balloon. The standard PTCA balloon is advanced to the lesion site.



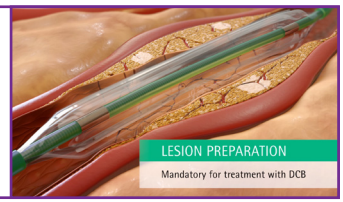
STEP TWO

The standard PTCA balloon is inflated, causing the lesion to crack.



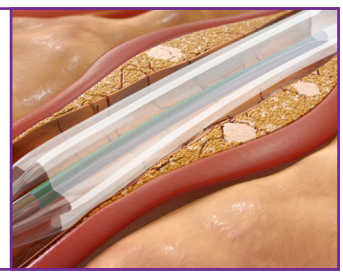
STEP THREE

The standard PTCA balloon is deflated and removed.



STEP FOUR

The DCB is advanced to the lesion site as quickly as possible. As soon as the balloon enters the bloodstream, the drug, paclitaxel will become active.

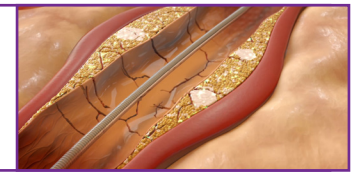


STEP FIVE

The DCB is inflated for 30 seconds at nominal pressure, paclitaxel with the help of its excipient iopromide, is instantly absorbed into the vessel wall.

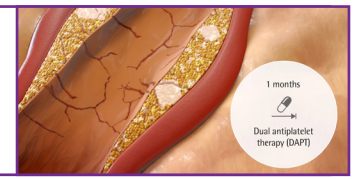
STEP SIX

The DCB is deflated and removed from the vessel, leaving nothing behind.



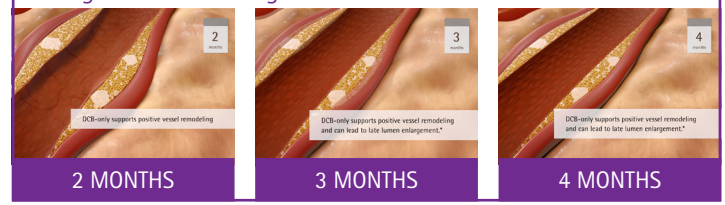
STEP SEVEN

1 month DAPT regime begins[8,9,10]



FOLLOW UP

If follow up is performed, positive remodelling and late lumen enlargement of the target vessel can be seen[8]



SEQUENT® PLEASE NEO

CLINICALLY PROVEN SECOND GENERATION DCB CATHETER WITH:

- Advanced crossing properties
- Improved pushability and deliverability
- Hydrophilic shaft coating
- Improved balloon profile and reduced balloon wall thickness
- Paclitaxel and Iopromide coating
- Effective drug release into the vessel wall
- Homogenous drug delivery

SEQUENT® PLEASE NEO HANDLING TIPS

- Pre-dilate the target lesion with adequate lesion preparation
- The DCB is for intended for a single dose transfer of paclitaxel
- The DCB can be used as a standard PTCA balloon following delivery of the drug, if required
- Sizing: 2 – 4 mm longer than pre-dilated area both distal and proximal to the lesion
- Balloon-vessel-diameter ratio: 1.0-1.0.
- Position the DCB at the lesion site as quickly as possible after entering the bloodstream
- Inflate once at nominal pressure for 30 seconds
- Do not bend, touch or wipe the balloon
- Do not expose the balloon to any fluids

SEQUENT® PLEASE NEO ADVANTAGES

NO UNNECESSARY STENT IMPLANTATION:

- No inflammation due to a foreign body implant
- No risk of stent related complications e.g. ISR or stent thrombosis
- No stent-related limitations for further treatment, if required
- No stent edge effect

EFFICACY OF DCB:

- Enables positive remodelling[1]
- Keep natural vessel vasomotion
- 1 month DAPT[1,2,3]

WHAT IS THE KEY MESSAGE?

Drug Coated Balloons will not completely replace drug eluting stents – drug eluting stents will continue to play a crucial role within coronary angioplasty.

DCBs can be used successfully in many indications outside of ISR and therefore are an alternative treatment option without stent-related disadvantages.

Patient-centered outcomes remain at the heart of clinical care and treatment options. Across Europe and the UK, the use of the DCB-only approach is increasing. Therefore, if a patient was eligible for the DCB-only approach and could avoid a metal implant, is it always necessary to implant one?

SEQUENT® PLEASE NEO
ORDERING INFORMATION

Balloon Diameter	Balloon Length						Nominal Pressure	Rated burst Pressure
	15 mm	20 mm	25 mm	30 mm	35 mm	40 mm		
2.0 mm	5023210	5023220	5023230	5023240	5023250	5023260	6 atm	14 atm
2.5 mm	5023212	5023222	5023232	5023242	5023252	5023262	6 atm	14 atm
3.0 mm	5023214	5023224	5023234	5023244	5023254	5023264	6 atm	14 atm
3.5 mm	5023216	5023226	5023236	5023246	5023256	5023266	6 atm	14 atm
4.0 mm	5023217	5023227	5023237	5023247	5023257	5023267	6 atm	14 atm

SEQUENT® PLEASE NEO
TECHNICAL DATA

Proximal shaft	1.9 F
Distal shaft	2.5 F
Usable length	145 cm
Balloon crossing profile	0.033" - 0.037"
Lesion entry profile	0.016"
Guiding catheter compatibility	5 F standard guiding catheter
Guidewire compatibility	0.014"
Rated burst pressure [RBP]	14 atm

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