**DCA + Stenting**

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a. Objectives of DCA + Stenting

Strategies of stenting after debulking using Directional Coronary Atherectomy (hereinafter DCA) are classified into two groups. One group is similar to primary stenting, following the idea of so-called "DCA debulking + stenting" (represented by Stenting after Optimal Lesion Debulking (SOLD) or the "Atherectomy before Multilink Stent Improves Lumen Gain and Clinical Outcomes Study (AMIGO)", etc.) in Europe and America.

This kind of stenting strategy is designed to achieve a larger initial lumen diameter than primary stenting alone, by debulking or partially debulking plaque, depending on the case, using DCA, solely as a preliminary treatment to facilitate easier insertion or expansion of stent(s). In this report, we call it "Pre-stent DCA Debulking".

In Japan, in contrast, a unique form of Intravascular Ultrasound- (IVUS) guided aggressive DCA (e.g. the Adjunctive Balloon Angioplasty After Coronary Atherectomy Study (ABACAS)) has been developed. Other strategies for DCA + stenting should be compared to this aggressive form of DCA. The objective of this group of strategies is to place additional stent(s) and therefore prevent restenosis after DCA. This report hereafter will call it "DCA + Adjunctive Stenting". Specifically, stents in these strategies are positioned so as to suppress vessel constrictive remodeling after DCA. This approach may also induce neo-intimal proliferation, so it is not yet certain whether this strategy is more effective for reducing restenosis in all lesion types, when compared to DCA alone.

At this point in time, maximum debulking using DCA is thought to be more advantageous whether as part of "Pre-stent DCA Debulking" or "DCA + Adjunctive Stenting". The selection of a strategy is based on the classification or status of the target lesion; complex lesions, such as calcified lesions or chronic total occlusions (CTOs) are often difficult to treat primarily with DCA alone; Pre-stent DCA Debulking may be a suitable approach for these lesions. On the other hand, "DCA + Adjunctive Stenting" done with primary DCA and followed by Adjunctive Stenting, is thought to be suitable for eccentric or bifurcation lesions, ostial lesions without a high degree of calcification; etc.

This report describes these two strategies for DCA stenting.

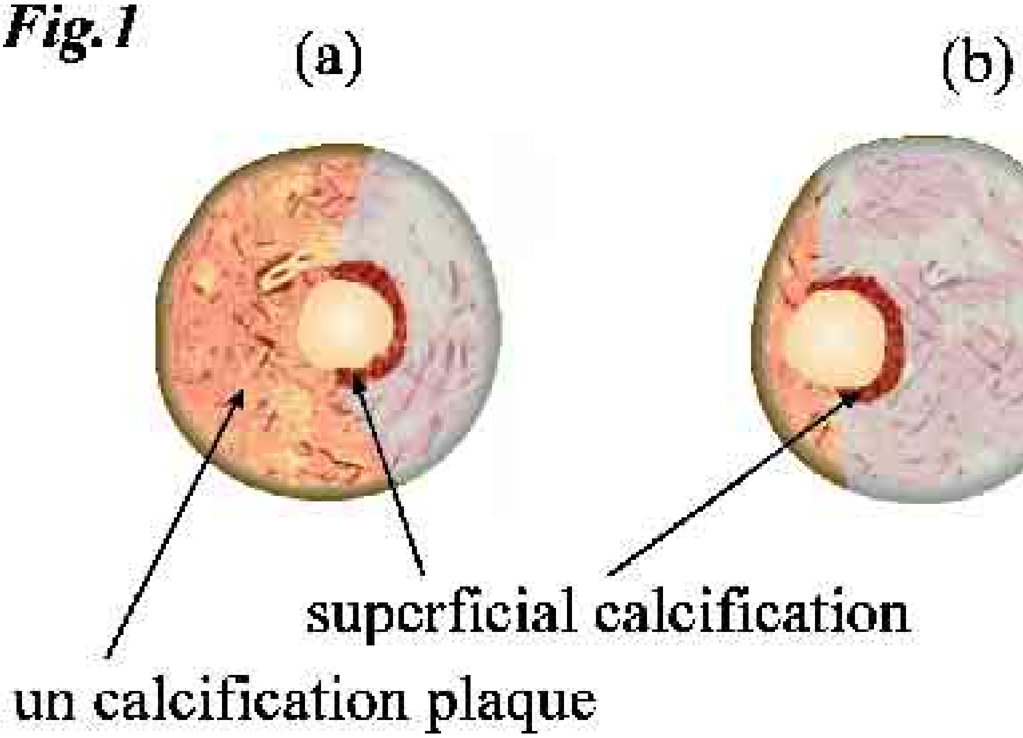
b. DCA + Adjunctive Stenting

The objective of DCA + Adjunctive Stenting is to prevent restenosis after aggressive IVUS-guided (primary or optimal) DCA. Specifically, the purpose is to prevent chronic-phase vessel constrictive remodeling by obtaining a greater initial lumen diameter than in a simple DCA procedure.  Caution is advised, however, since neo-intimal proliferation inside the stent is accelerated by the use of additional stents. Using DCA + Stenting may be contra-indicated or useless depending upon lesion morphology. Pre-conditions for DCA include the following:

1. Target lesions should be located in comparatively large blood vessels (>/=3mm angiographically; >/=3.5 mm by IVUS) due to the nature of the devices used in DCA; and
2. for primary IVUS-guided DCA, there should be no superficial calcification >180°

When a non-Calcified lesion is located on the opposite side to the calcification (see Fig. 1a), debulking is appropriate at that site even if>180°superficial calcification is observed on the same IVUS view. However, where little or no contra-lateral plaque is present (see Fig. 1b), debulking with DCA is not appropriate. Moreover, device insertion itself is difficult and may have to be abandoned due to the possible risk of complications such as dissection. In short, aggressive DCA should be conducted under IVUS guidance only if these conditions are present.

*Fig.1*




Aggressive IVUS-Guided DCA:
First, plaque distribution, i.e. direction of the growth of the plaque deposit, as well as the width of the long axis of the deposit in the vessel cross-section, should be precisely determined using pre-operative IVUS (with a smaller balloon after pre-dilation, if required) imaging.

Ideally, IVUS imaging should always be performed using a motorized auto-pull back system to avoid rotational unevenness. The distribution of plaque is generally determined by the direction of bifurcation and the position of each branch of the target vessel. For left main trunk and left anterior descending side-branches, the direction can be accurately identified by examination of the septal/diagonal branch and the bifurcation of the circumflex artery. For these vessels, the smallest differences from individual to individual are seen in the bifurcation angle of the first diagonal branch, while the greatest differences (which should be noted) are seen in the bifurcation angle of the circumflex artery. By examining each bifurcation angle from at least three views, RAO (Right Anterior Oblique) caudal, RAO cranial and LAO (Left Anterior Oblique) cranial, using IVUS images, the direction of the proximal and distal spread of the plaque can be determined. After that, DCA is performed using the RAO caudal view when the lesion is in the left main trunk or proximal anterior descending branch; it is performed using the RAO cranial if the lesion is in the middle portion of the vessel or distal to that segment.

The LAO cranial view should be avoided because of the inevitable deterioration of the fluoroscopic image and because of the unreliability of depth perception due to the compressed view of the image in DCA. Its use should be restricted solely to the reconfirmation of the direction of plaque growth.  As there are relatively few branches in the right coronary artery, as is also the case with the LAD, only the 4PD or the RV branch can be used as a rough guide. There are, however, considerable differences among individuals in the bifurcation of the RV branch; careful observation of the angiogram is a must.

It is recommended not to rely solely on bifurcations as references in determining vessel direction, but always to use them in conjunction with additional information such as the positional relationships between the guiding catheter (or the vessel lumen) and the IVUS catheter, or between the IVUS catheter and the wire. There is always some kind of tangential bifurcation (at the point of separation into right and left in every RV branch) depending on the angiographic view used.  Angiography just before the IVUS pull-back can be very useful.

In the case of an RCA lesion, DCA from the LAO view alone is generally recommended. Caution is advised, however, since the proximal vessel may be substantially extended insertion of the DCA catheter. As a result, the appearance of the relative positions of the vessels may be distorted. The direction the left circumflex artery is difficult to determine since it has the greatest anatomical variation.

In each case, the bifurcation of branches is identified using the RAO caudal, LAO cranial or LAO caudal view. At the same time, the direction of the vessel is determined, based on the relative positions of the vessel and catheter or the wire. Then, DCA is performed using the RAO (Right Anterior Oblique) caudal or the AP caudal view. It is also useful, for any target branch, to perform a single First Cut in a certain direction and then to fine-tune the device tip accordingly by confirming the vessel direction via the IVUS image immediately after that cut.

Cutting can be performed aggressively under repeated IVUS, if required. Increasing pressure gradually from the starting point of 10psi is recommended. The end point assay should be performed via IVUS rather than angiography. A remaining plaque area</=50% (if pre-operative compensatory vessel remodeling is not extensive), and a lumen area of at least $8mm^2$ (if remodeling is extensive and the pre-operative plaque area was extremely large) should be the goal.

Adjunctive Stenting:
Once DCA has been successfully conducted, adjunctive stenting is next. In this procedure, it is necessary to select the type of the stent paying close attention to lesion morphology, especially the degree of tortuosity and whether or not side-branch bifurcation is present (as well as the length of the lesion). Caution is advised since stent sizing should differ depending on proximal and distal vessel reference diameters under IVUS, as well as the degree of remodeling at the lesion site.  Sizing based solely on angiographic view may result in undersizing. In any case, the use of high pressure for stent expansion is usually not necessary; and should be avoided. As a considerable volume of lumen should already have been acquired, full expansion of the stent usually can be expected with minimal dilation pressure, typically 6~8atm. In the case of intensely remodeled lesions, only if the lesion area itself is too narrow for the stent selected, should post-dilation be performed and using the largest balloon possible. Finish the procedure after confirming adequate apposition of the stent struts to the vessel wall using IVUS.

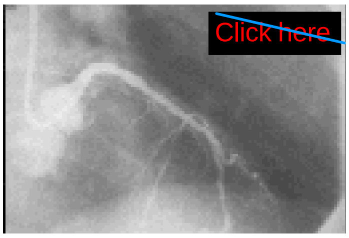
Case Presentations:

<Case 1>

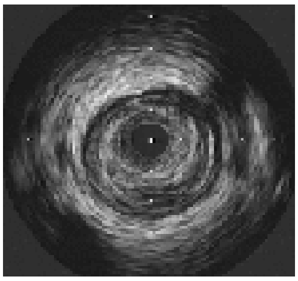
A 60yo male, with angina, and Left Anterior Descending Artery (LAD) Single Vessel Disease (SVD) : (~~video~~-a) 99% stenosis was observed in the LAD mid-portion. The reference vessel diameter on QCA (Quantitative Coronary Angiography) was 3.01 mm; lesion length was 18.7 mm. IVUS revealed a fibrous-fatty plaque without calcification (see IVUS-a). DCA was performed with a 7F GTO starting at 10psi. Debulking was conducted under IVUS guidance, while increasing the pressure gradually up to a maximum of 40psi. A total of 24 cuts were made and stenosis of only 4.8% observed on QCA. Good debulking, LA (lumen area) 8.7mm$^2$, with the residual area stenosis 51.6% observed on IVUS (see IVUS-b). The procedure was concluded, after implantation of a Multilink stent (3.5mm) at 6atm. No acute in-stent proliferation was observed on QCA. An enlarged final LA of 9.2 mm$^2$ was observed on IVUS (see IVUS-c). Lumen gain was 8.0 mm$^2$, of which decrease in plaque area was 5.8 mm$^2$ (73%) and enlarged vessel area only 2.2 mm$^2$ (27% ) (~~video~~-b). Six months after treatment, stenosis had increased 8.8% on QCA and in-stent neo-intimal proliferation (see IVUS-d) was only 0.2 mm$^2$ by IVUS.

**1-~~video~~-a**

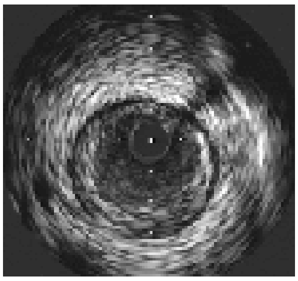

**1-~~video~~-b**



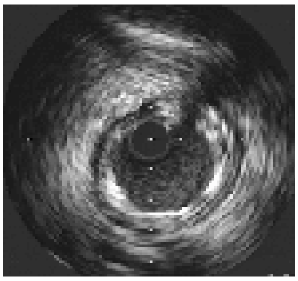

**1-IVUS-a**



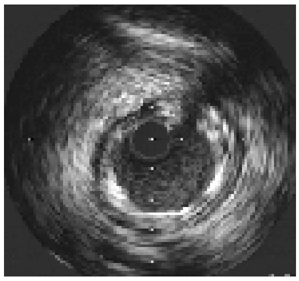
**1-IVUS-b**



**1-IVUS-c**



**1-IVUS-d**



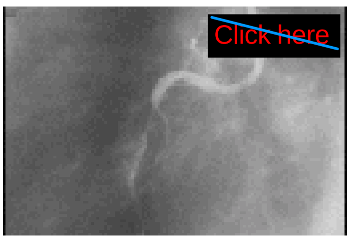
<Case 2>

A 66yo male, angina, SVD at Right Coronary Artery (RCA).

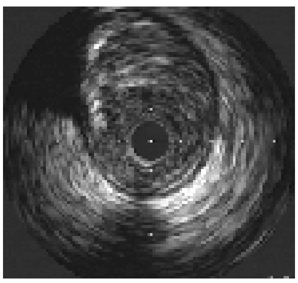
(~~video~~-a) Diffuse stenosis (99%) was observed in the RCA mid-portion.

Reference vessel diameter on QCA was 3.44 mm and lesion length was 18.1 mm. Under IVUS the lesion was seen to consist of fibrous-fatty plaque accompanied by superficial/deep calcifications that</=45°but the vessel area was as large as 24mm$^2$ (see IVUS-a). DCA was performed starting at 10psi using a 7F GTO. Since successful primary DCA was not achieved solely by debulking under IVUS guidance with pressure gradually increased up to a maximum of 40psi (see IVUS-b), a larger type of 7F-Graft athero-catheter was then used. A total of 26 cuts were made and a 0% stenosis was seen on the QCA image. The IVUS results,

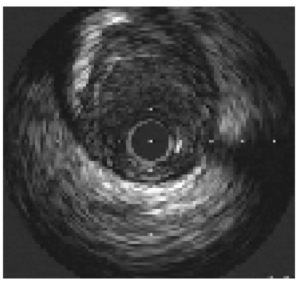
**2-~~video~~-a**




**2-IVUS-a**

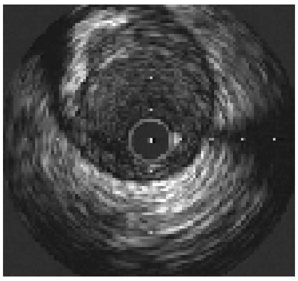


**2-IVUS-b**

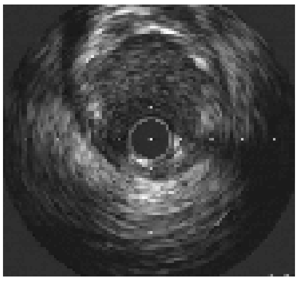


however, suggested LA was 7.7 mm$^2$, with residual area stenosis rate of 68.5% (IVUS-c). These unsatisfactory results may have been caused by the very large vessel area. The procedure was concluded with a 4.0 mm Multilink stent being implanted at 7atm. The result was sufficient enlargement, a final LA of 13.4 mm$^2$and a residual area stenosis of 47.0% (see IVUS-d). (~~video~~-b) Stenosis of 42.6% and some late loss was observed on QCA 6 months after treatment, but LA was 7.6mm$^2$ and no restenosis was observed under IVUS.

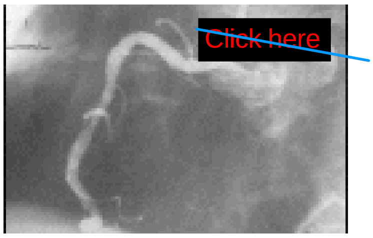
**2-IVUS-c**



**2-IVUS-d**



**2-~~video~~-b**



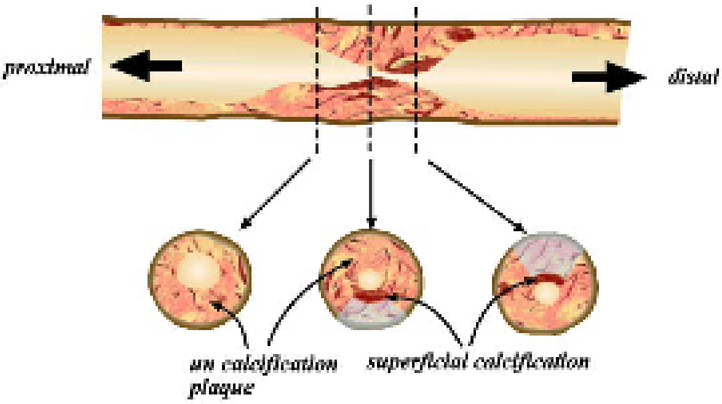

c. “Pre-stent DCA Debulking”

Lesions that have a high degree of calcification and chronic total occlusions ultimately need to be treated with stenting. Pre-Stent Debulking is intended to make the insertion of the stent easier, to allow full expansion of the stent with minimum vessel injury to the wall, to obtain a larger initial lumen diameter compared to primary stenting and as a result, to reduce the long-term restenosis rate. For this technique, debulking is performed where primary debulking, described above, will not or has not worked. DCA should be partial, moderate debulking. The strategy of debulking before stenting, which is often used in Europe and America, corresponds to this method. It is advised, however, that partial moderate debulking be restricted to those cases in which primary DCA is difficult or not indicated, since it is generally desirable to perform as much debulking as possible.

Calcified Lesions:

Calcified lesions are among the most difficult lesions to treat with DCA. They are not easy to stent, either, since calcification often can prevent the stent from expanding. For this reason, it is largely considered advantageous for stent deployment, if some plaque can be removed, even if only a little, before implantation of the stent. There are some lesions, however, for which the DCA approach may be possible even if they have some degree of calcification. As described above, even if the superficial calcification is>180°(note *), it is possible to perform DCA, if there is a reasonable amount of plaque on the opposite side of that calcification. Even a calcified lesion can be debulked, together with non-calcified plaque, working from the proximal region in cases where the non-calcified plaque offers a space for the DCA cutter within the calcified lesion and proximal to it (see Fig. 2).

*Fig.2*



It is extremely important to move the cutter as slowly as possible by observing it in the device window. Rapid movement of the cutter will not only cause the cutter to slip on the surface of the calcification, but also makes it more difficult to cut the plaque. It is also important to increase balloon pressure gradually since the delivery of the athero-cath itself often causes resistance, which can result in a small dissection of the vessel, just as the tip reaches the lesion. Rapid increase in balloon pressure in such cases allows the balloon to expand into the dissection cavity instead of expanding against the cell wall opposite the target plaque. This results in failure to press the device window onto the plaque so that the cutter can attack it. It may be necessary to begin debulking by starting from 0psi, depending on the situation. In any case, 0psi is required to facilitate delivery of the atherocatheter to the target lesion. If the calcification, including the proximal part of the lesion, prevents delivery, pre-dilation at high pressure (a 2.0-2.5mm conventional balloon) should be performed (cautiously, to avoid creating large dissections proximal or distal to the lesion). Alternatively, a preliminary rotational atherectomy can be performed.

Chronic Total Occlusions:
A CTO is a lesion where stent placement is mandatory in order to prevent re-occlusion (except when in a small vessel). It is also likely to be plaque-rich because it is 100% occluded. Pre-Stent debulking may therefore be a natural strategy for CTOs. CTOs indicated for DCA are those in which the vessel at the occlusion site is comparatively large without extensive constrictive or negative remodeling or extensive calcification. When such CTOs are seen under IVUS, pre-Stent Debulking using DCA is the recommended strategy. This should be performed as aggressively as possible. Pre-dilation is performed using a conventional PTCA balloon if lesion morphology requires.

Debulking End-Points:
With this type of lesion, it is often difficult to define your endpoint of “residual plaque area of 50%” Of course, closer to 50% is ideal but less than 60% should suffice as a rough standard. In fact, the catheter itself often breaks during repeated debulking.

The most important consideration is whether a sufficient volume of plaque has been removed. In other words, if the excised tissue volume is not sufficient, the effect of expanding the occlusion may result in Dotter’s effect, negating the intended effect of the debulking.

Stenting:
The criteria for stent selection are described above. If the remaining calcific burden is extensive, a slotted tube-type stent, which has strong radial force, will most likely be preferable. For sizing, caution is advised in inserting too large stent at the outset because plaque, especially calcified plaque, is often accompanied by a small area of stenosis (which does not require stenting) proximal and distal to the lesion. It is often recommended to set dilation pressure almost to minimum dilation pressure, or to implant a smaller stent, followed by an application of high pressure only within the stent, or by post-dilation using a larger stent. Whatever the case, in contrast to previous reports, where debulking is not the primary strategy, the pressure used to deploy the stent needs to be increased.

It is generally important to evaluate accurately minimal stent area and its symmetry index using the IVUS, although they may have already been determined from the degree of calcification. Ideally, a minimum stent area of $10mm^2$ or greater, and a symmetry index of close to 1.0, are preferable.

Case Presentations:

<Case 3>

Male, aged 55, old myocardial infarction, LAD with single vessel disease (SVD).

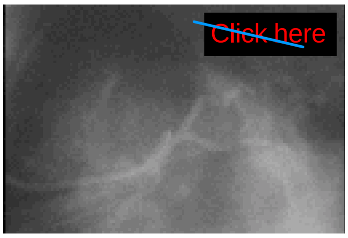
(~~video~~-a) LAD was occluded at the ostium (occlusion duration one year). Reference vessel diameter was 3.02 mm and lesion length was 20.8 mm on QCA.

(~~video~~-b) Lesion was crossed with a stiff wire under contra-lateral angiographic-guidance, followed by a pre-dilation by 1.5 mm balloon and then IVUS. The obstruction found to be fibrous plaque, accompanied by deep calcification. The vessel area was 10.5mm$^2$ with evidence of constrictive remodeling proximal and distal to the lesion (see IVUS-a).

(~~video~~-c) A total of 36 cuts were made using a 7F GTO and 7F-graft, starting from 10psi up to a maximum of 40 psi. As a result, QCA showed stenosis of 6.1% and minimal luminal diameter (MLD) of 3.03 mm. IVUS showed LA 8.5 mm$^2$ and residual area stenosis of 36.8%, which is a good debulking result for a CTO (see IVUS-b).

**3-~~video~~-a**

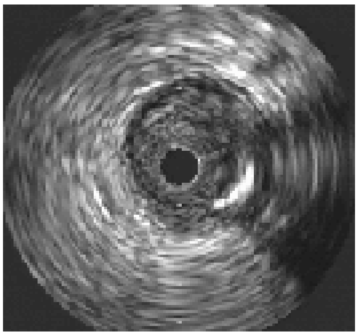

**3-~~video~~-b**



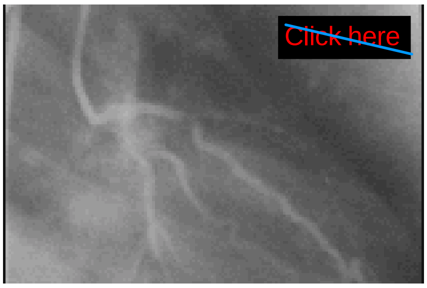

(~~video~~-d) The procedure was concluded after implantation of a 3.5 mm Multilink stent at 8atm. An enlarged final LA of 9.8 mm$^2$ was observed under IVUS (see IVUS-c).

(~~video~~-e) QCA at 6 months post- treatment showed MLD of 2.6 mm and stenosis of 24.7%; no detectable restenosis.

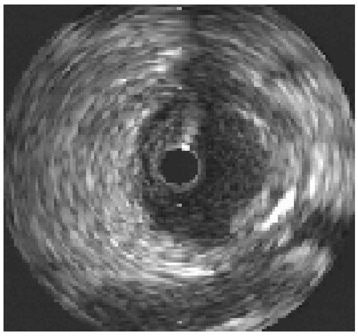
**3-IVUS-a**



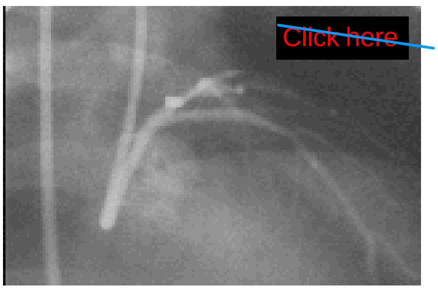
**3-~~video~~-c**



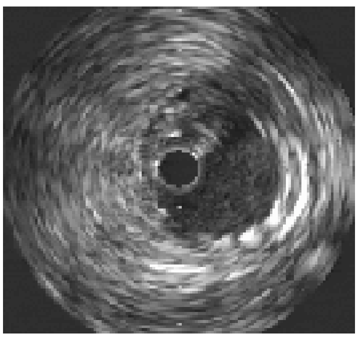

**3-IVUS-b**



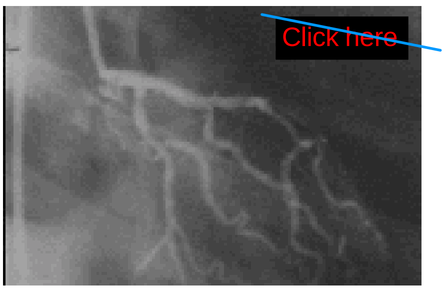
**3-~~video~~-d**




**3-IVUS-c**



**3-~~video~~-e**



<Case 4>

Male of 61, old myocardial infarction, SVD in RCA.

(~~video~~-a) The RCA was occluded in the mid-portion (occlusion duration three months). Reference vessel diameter was 4.33 mm and the occlusion length 30.3 mm on QCA.

(~~video~~-b) Lesion crossed with a stiff wire under contra-lateral angiography, followed by a pre- dilation (2.0mm balloon) and then IVUS, showing the obstruction was a huge calcification without soft plaque and the vessel area was as large as 29.2 $mm^2$ (see IVUS-a).

(~~video~~-c) A total of 22 cuts were made, using Flexi-Cut (L), starting from 20psi and increasing to a maximum of 60psi. Debulking was stopped midway through the procedure, due to device fracture.

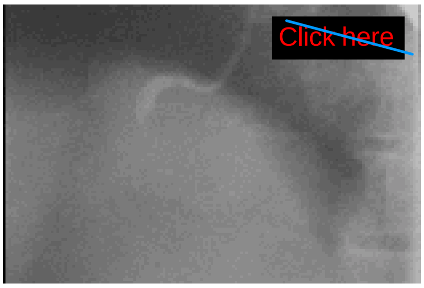
The minimum LA was enlarged to 8.6 $mm^2$ and the excised tissue volume was 34.7 mg.

(~~video~~-d) A 4.0x 25mm NIR stent was immediately placed at 8atm, then post-dilated to a maximum of 14atm, using the same stent balloon.

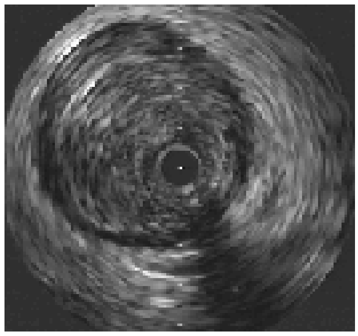
(~~video~~-e) The completed procedure resulted in observable stenosis of 0% on QCA. The final LA was 15.2 $mm^2$ on IVUS; sufficient enlargement was obtained (see IVUS-c).

**4-~~video~~-a**


**4-~~video~~-b**

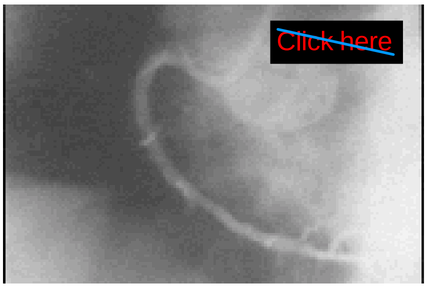



**4-IVUS-a**



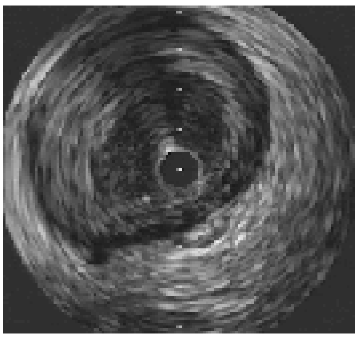
**4-~~video~~-c**


**4-~~video~~-d**

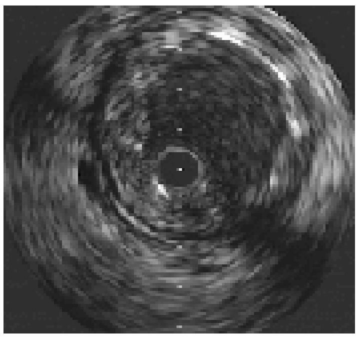



**4-~~video~~-e**


**4-IVUS-b**



**4-IVUS-c**



### d. Summary

This report describes the principles of both “DCA + Adjunctive Stenting” and “Pre-stent DCA Debulking”, as well as the methods involved. It is clear that a number of important points remain to be clarified. Two such points are whether or not Adjunctive Stenting is required after primary DCA, and when; another is how to determine the appropriate end-point of debulking before stenting (for Pre-stent DCA Debulking).