Expected Roles of Plasma-Mediated Ablation System in CTO PCI

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Disclosure

- Disclose potential conflicts of interest
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This presentation includes content on unapproved pharmaceutical products

What are the limitations of the mechanical guidewire

There are some uncontrollable issues for manipulation of the mechanical guidewire

1: Whipping motion

2: Tip deflection

3: Penetration

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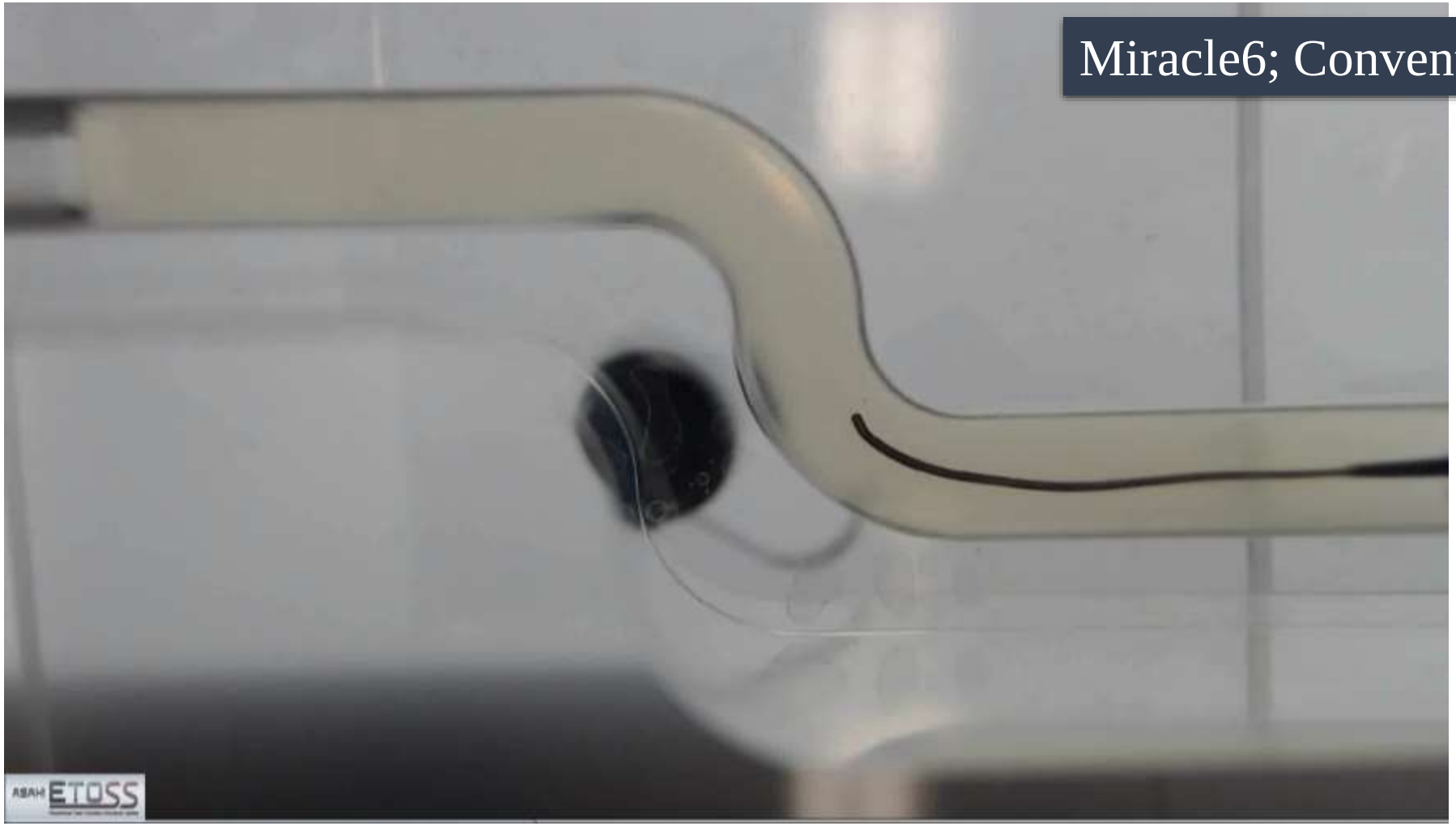
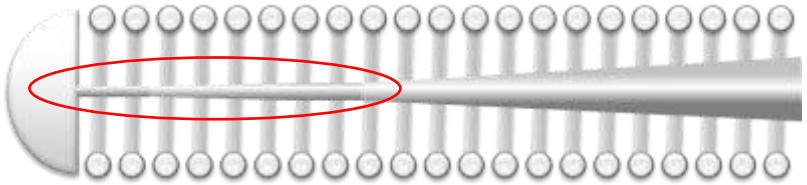
Whip Motion

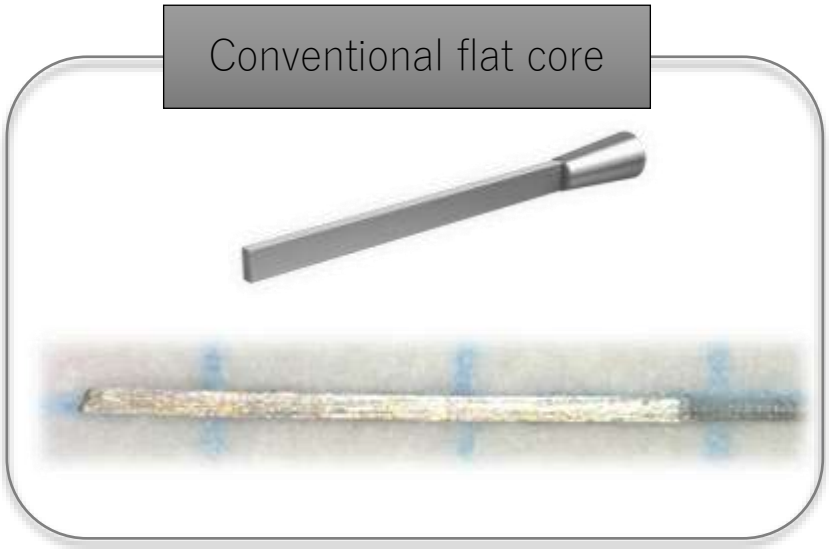


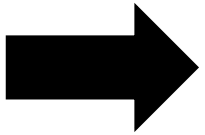
This is a whipping motion, which is a movement that cannot be kept in the direction you want to point it in.

Core Wire Design ➡ Torque response

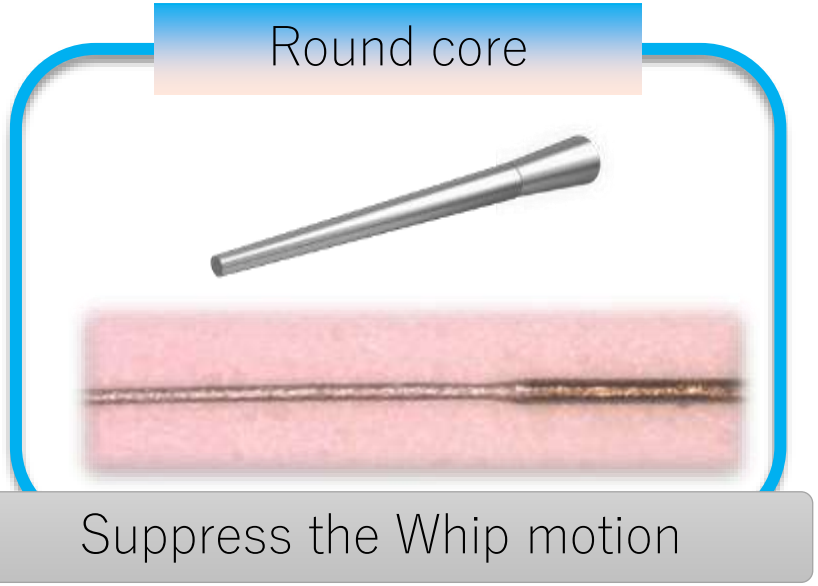


Conventional flat core





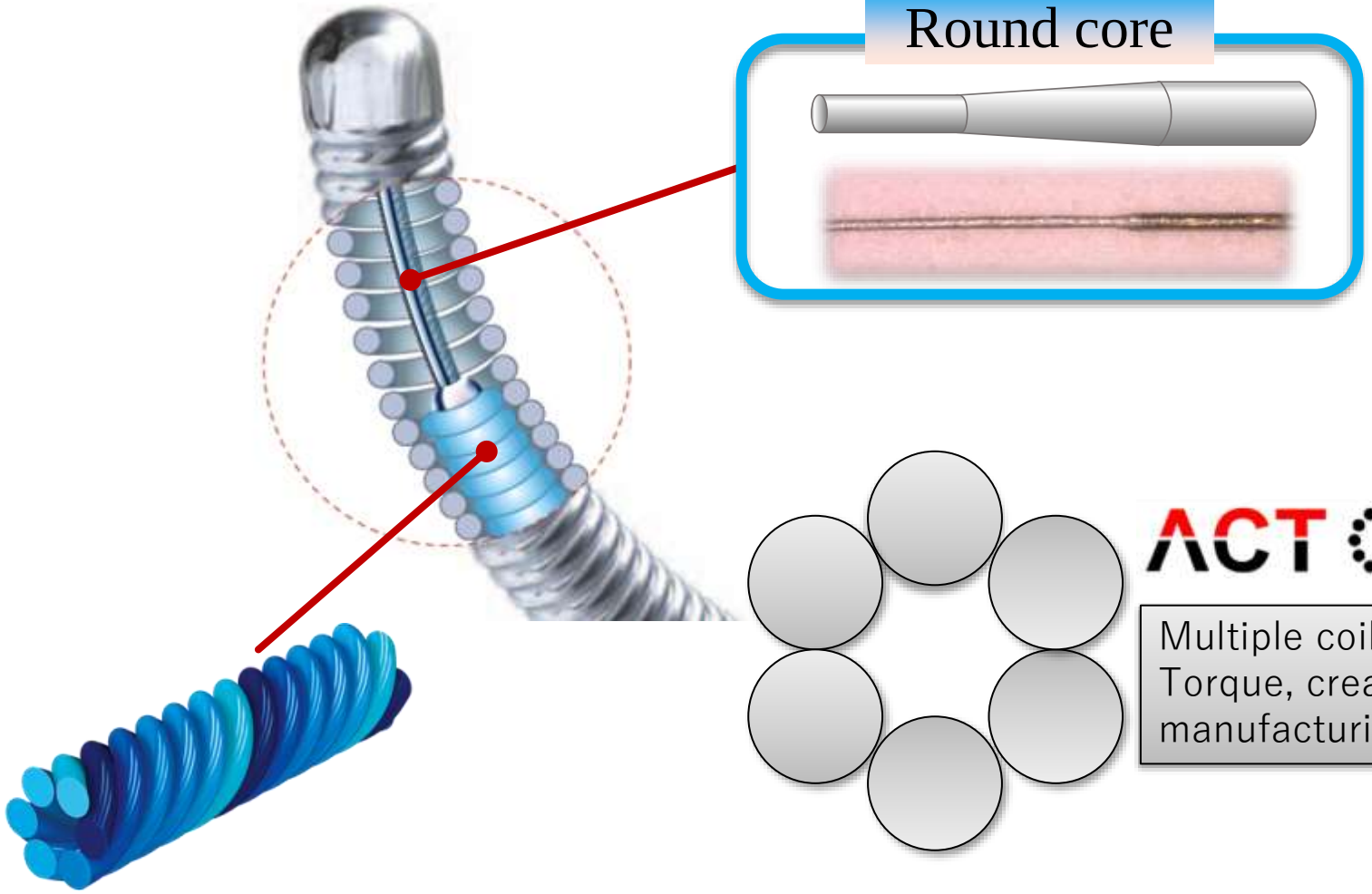
Round core



Suppress the Whip motion

Core Wire Design

- Having control over whip motion
- One-to-one torque control



Round core

SION series
Gaia series
XT-R
XT-A

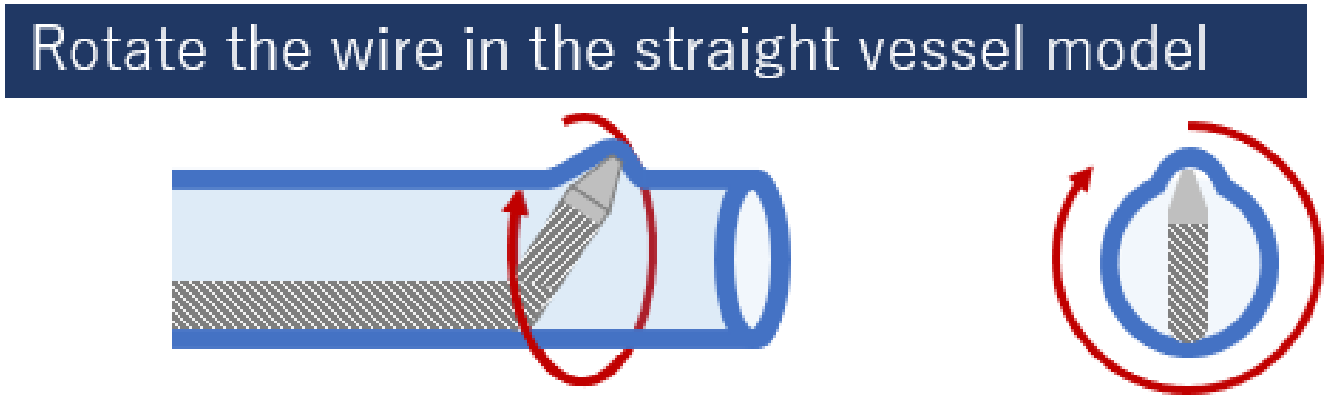
ACT ONE®

Multiple coil, superior in Anti-deformation and Torque, created by ASAHI INTECC's original manufacturing technology.

Asahi Intec's technology has created a composite core wire with an ACT one structure at the tip, which further improves torque response dramatically

Gaia Next 2, with its round core and Act one structure, is less prone to whipping, making it easier to control the tip

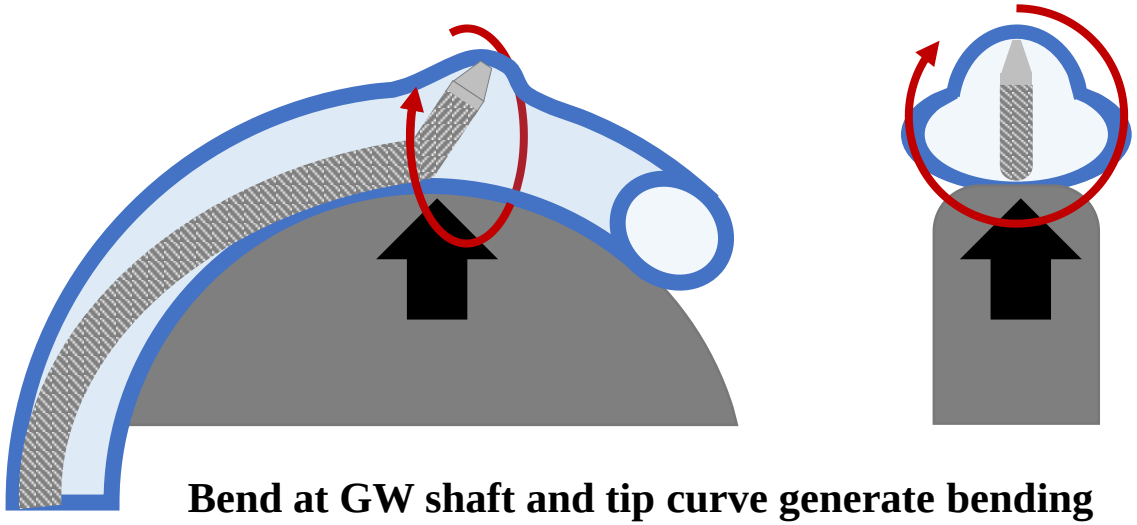
Straight vessel model



According to a new concept wire, Whipping will not occur if the GW shaft is straight in the straight vessel model

Bending vessel model

Rotate the wire in the oppressed and bending vessel model

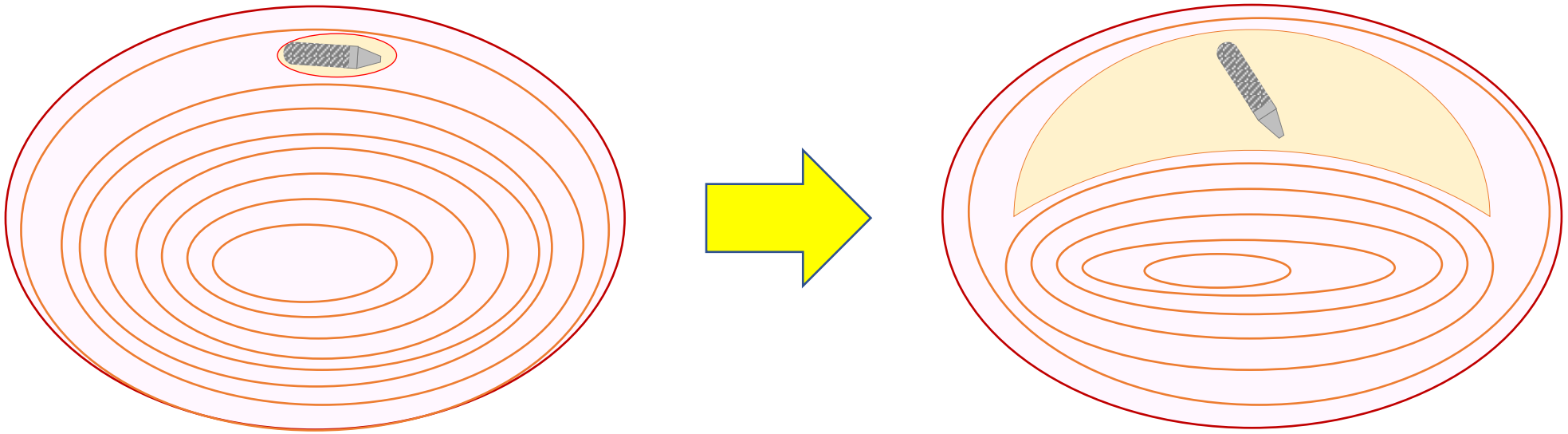


Bend at GW shaft and tip curve generate bending moment that results in whipping motion.

However, in a bending vessel, the bend at the GW shaft and tip curve generates a bending moment that results in whipping motion even with the new concept of CTO wire.

The problems caused by whipping motion

After rotation of the GW tip by whipping, a large space (semilunar space) is created

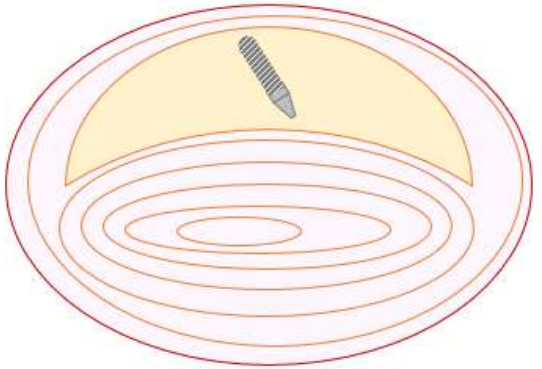


The problem with whipping is that the whipping motion creates a semilunar space in the laminar tissue. This means that whipping motion cannot be completely controlled with the current mechanical wire manipulation, which leads to the formation of a semilunar space.

What are the limitations of the mechanical guidewire

There are some uncontrollable issues for manipulation of the mechanical guidewire

1: Whipping motion



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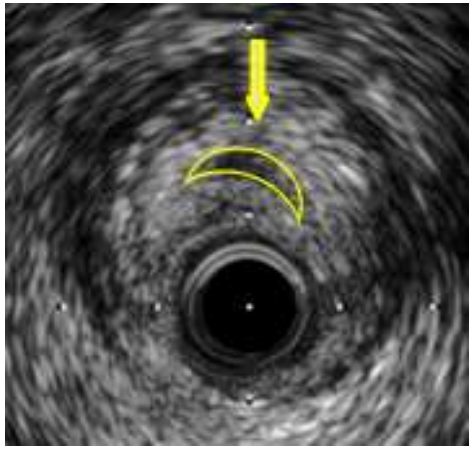
Large semi-lunar space



What are the limitations of the mechanical guidewire

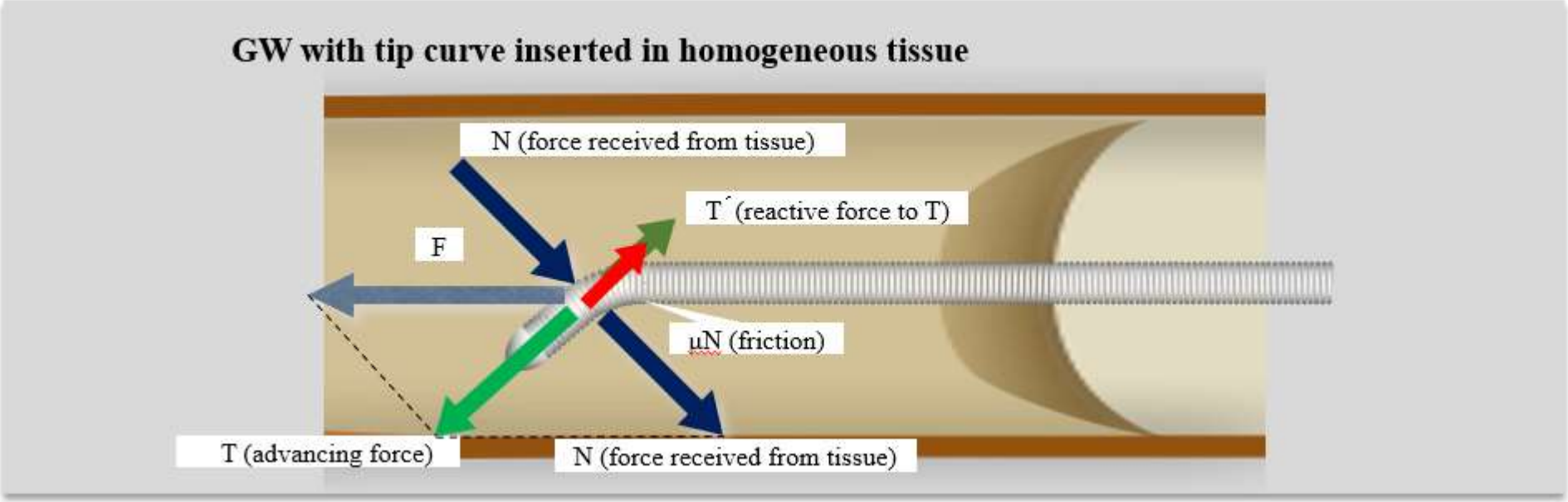
There are some uncontrollable issues for manipulation of the mechanical guidewire

1: Whipping motion

2: Tip deflection

3: Penetration

Tip Deflection



When a guide wire with a tip curve is inserted into uniform tissue.

(1) When the GW is pushed, a force (F) in the longitudinal direction is generated.

(2) The tip curve of the GW receives resistance (N) from the occluded lesion side to this pushing force F.

(3) The pushing force F is deflected to the propulsive force in the T direction by the force N received from the occlusion lesion. This is deflection.

(4) As a result, GW moves in the direction of the propulsive force T. When GW moves, frictional force (μN) and reaction force (T´) against the propulsive force is generated.

Various factors affect tip deflection

Lesion associated	Tissue hardness
	Tissue homogeneity
	Semilunar space
GW associated	Tip curve
	Penetration efficiency; tip diameter, tip load, coating
	Rigidity gap at GW tip
	Shaft rigidity

Various factors affect tip deflection

Lesion associated	Tissue hardness
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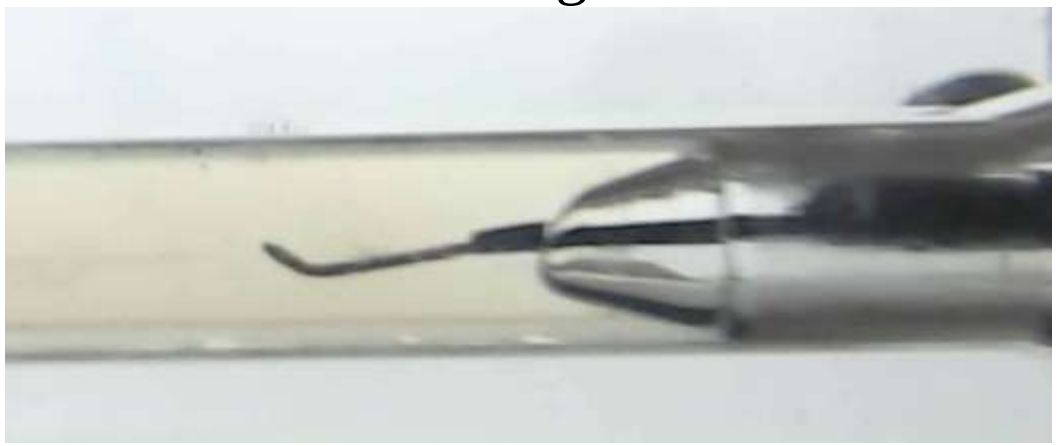
Tip Load

ETOSS 8000

Conquest Pro 12 〈12.0gf〉

Conquest Pro 12 with higher tip load tends to advanced straight.

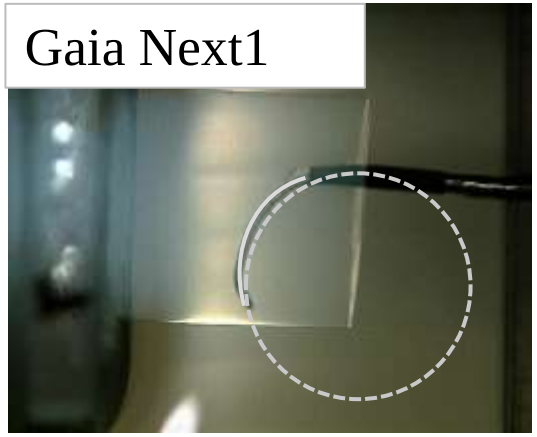
Gaia Next 1 〈2.0gf〉

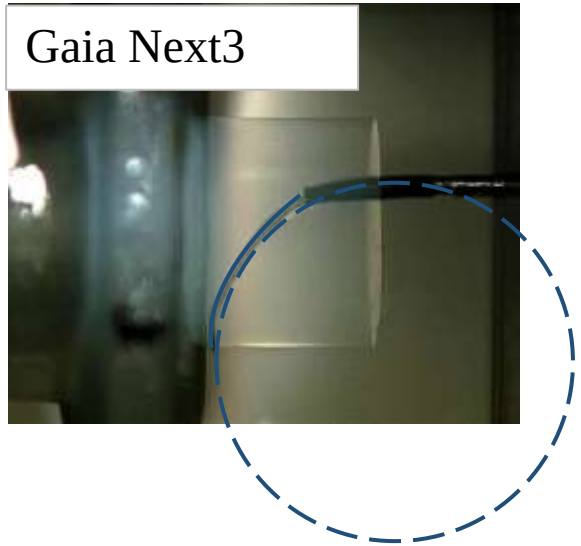


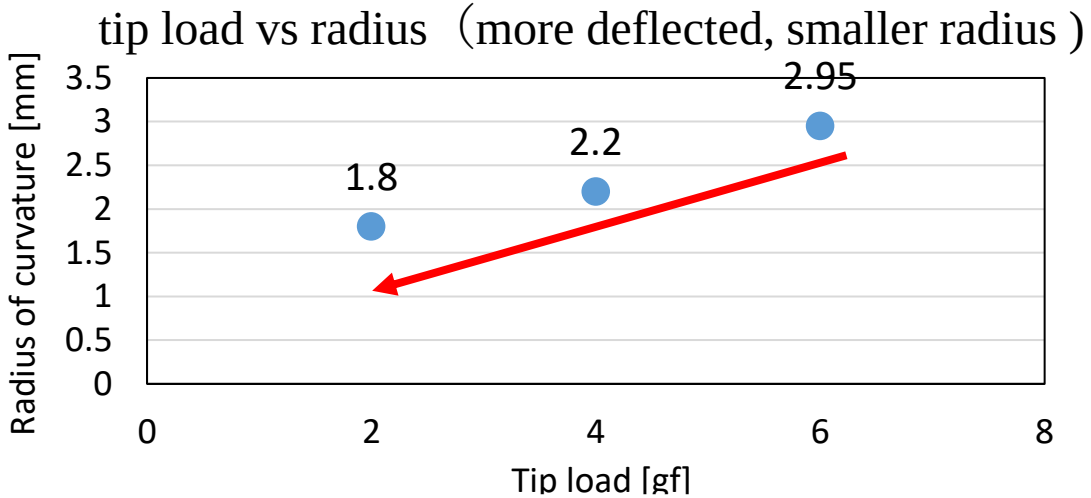
Gaia Next 1 with lower tip load tends to be deflected.

Tip Load

Correlation between tip Load and deflection







The smaller tip load, the more tip deflection.

Tip length

Miracle 6　〈1mm 45°〉

Miracle12 with shorter tip length tends to be less deflected.

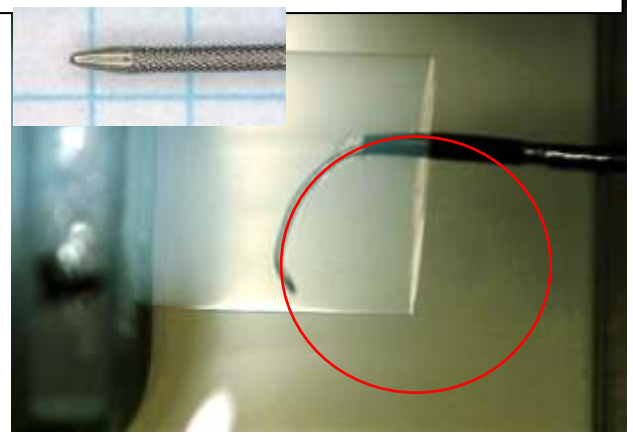
Miracle 6　〈2mm　45°〉

Miracle12 with longer tip length tends to be more deflected.

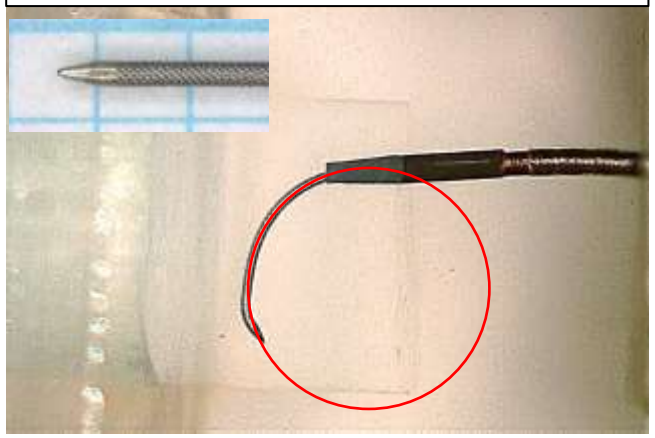
Tip Length also affects how it is deflected, as well.

Tip diameter

① Normal Gaia Next1 / 0.141mm

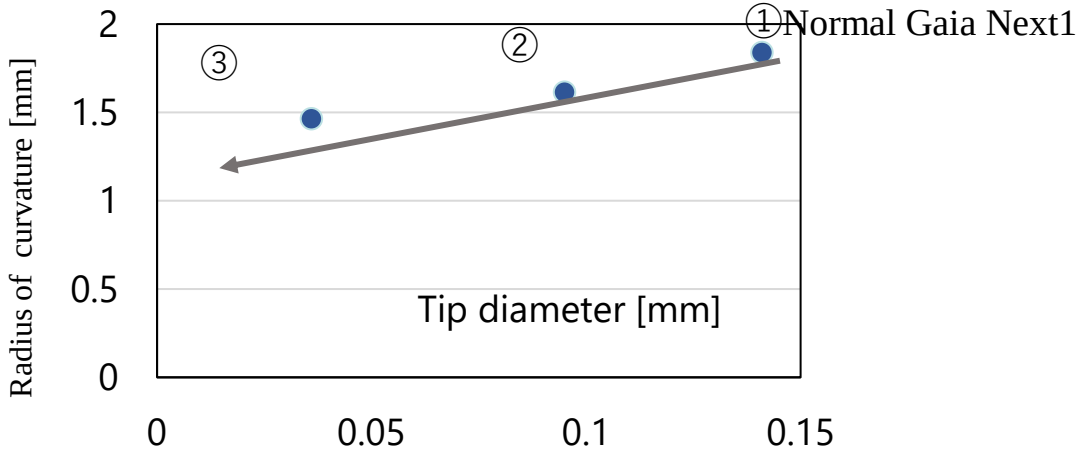


② Gaia Next 1 with 0.095mm tip



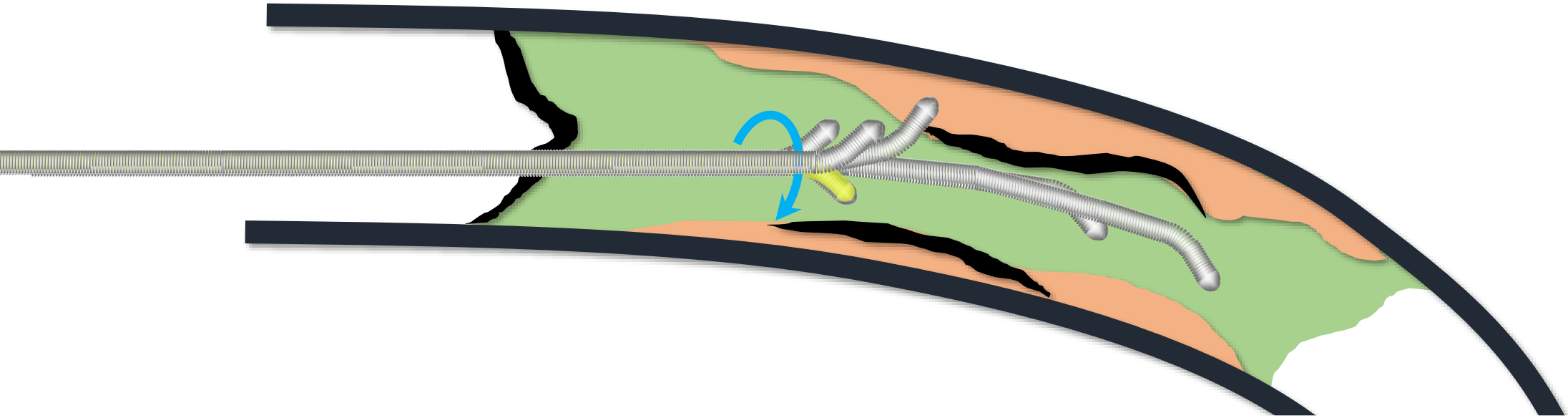
③ Gaia Next1 with 0.036mm tip

Diameter vs ㇾTip Deflection



The smaller tip diameter, the more tip deflection.

We consider these factors in our wire selection and tip shape and perform wire manipulation.



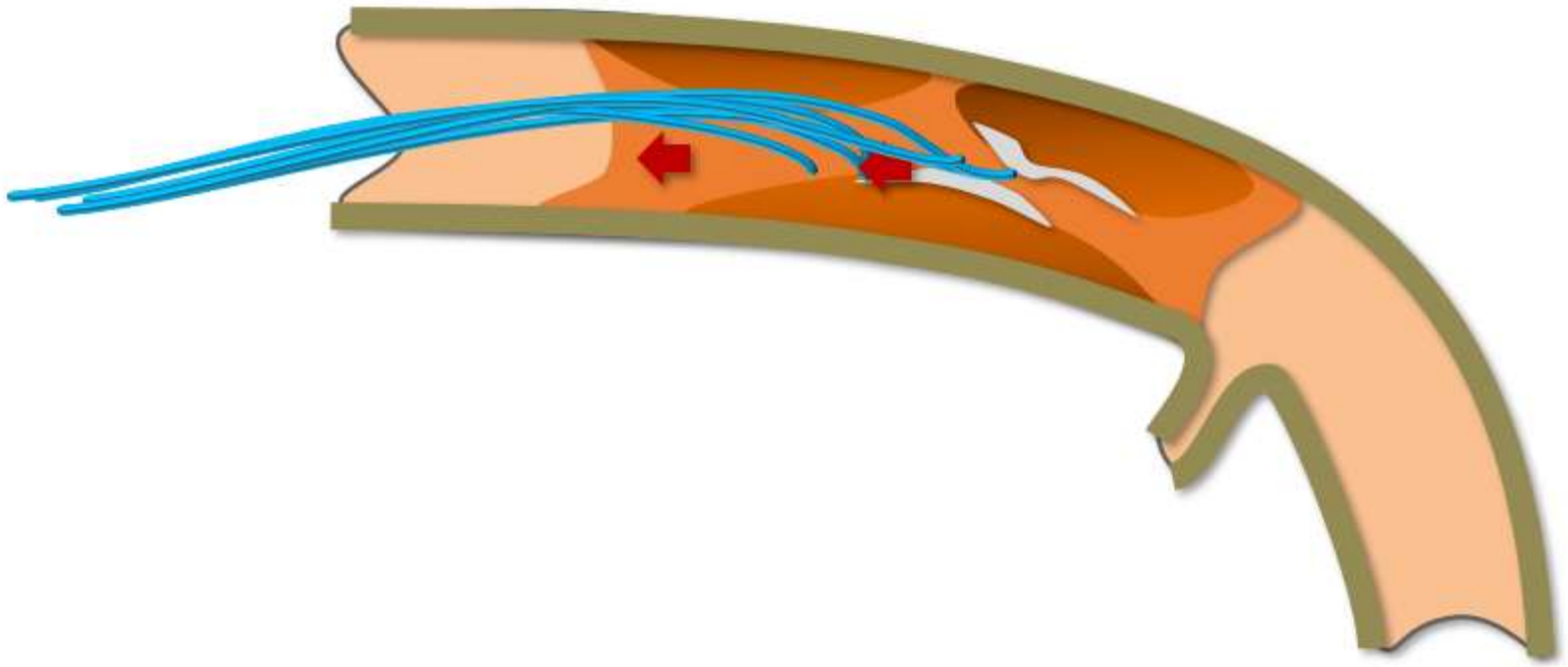
If the CTO's organization is uniform, it is possible to control deflection, such as with the Wire selection. But unfortunately, the factors involved in deflection are not the only ones involved in the Wire.

Various factors affect tip deflection

Lesion associated	Tissue hardness
	Tissue homogeneity
	Semilunar space
GW associated	Tip curve
	Penetration efficiency; tip diameter, tip load, coating
	Rigidity gap at GW tip
	Shaft rigidity

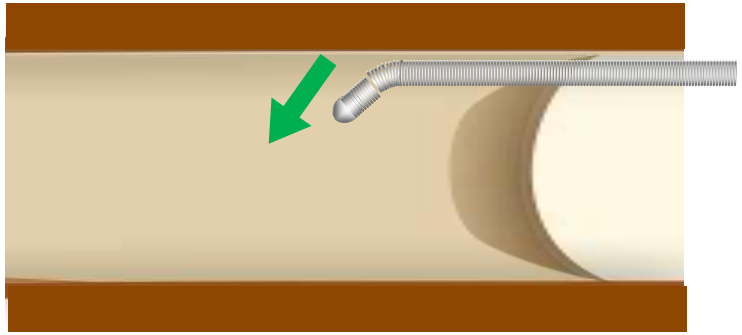
There are many factors involved in the lesson. These include lesion hardness, heterogeneity, and the semilunar space mentioned in the Whippin motion section. These factors on the lesion side are not within our control.

Lesion associated

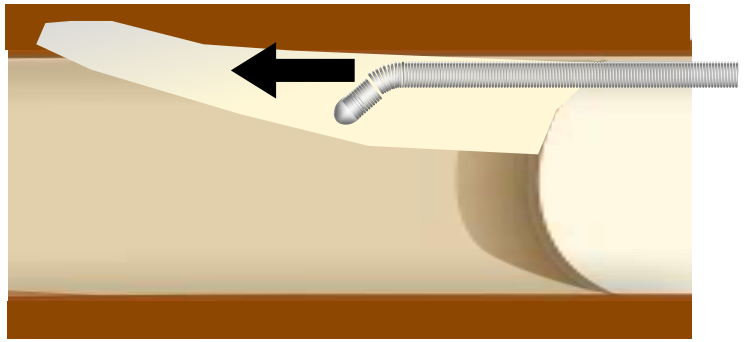


In general, the tissue in CTOs is often hard and heterogeneous, and we cannot observe the inside of the CTOs during operation. This means that it is difficult to control deflection.

In addition, tip deflection does not occur in some situation

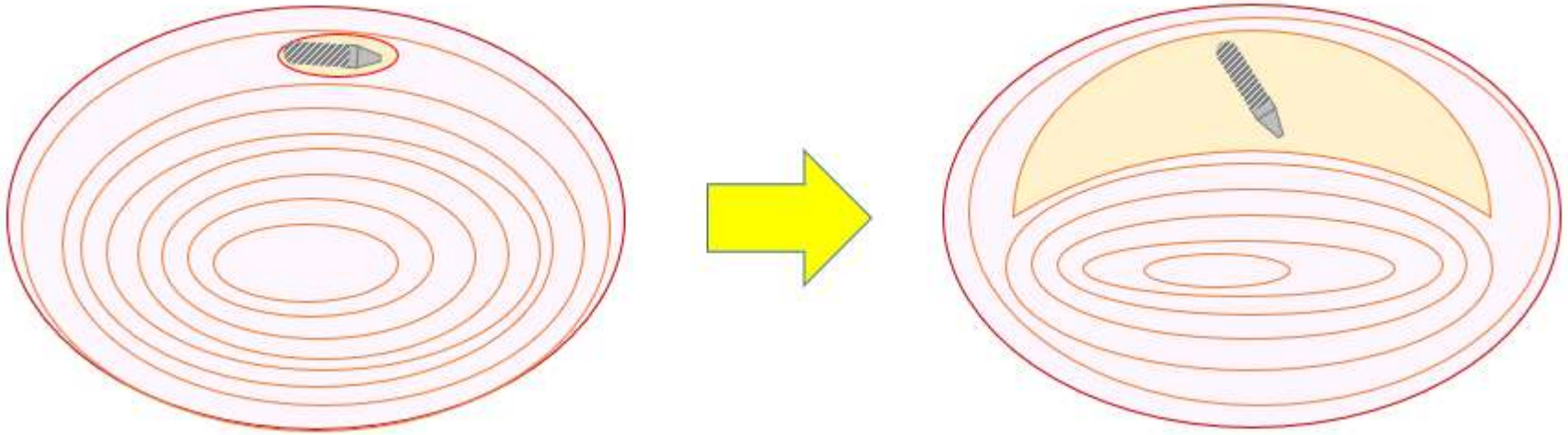


CTO wire can be controlled only inside solid tissue and a small space around the tip of the guidewire.

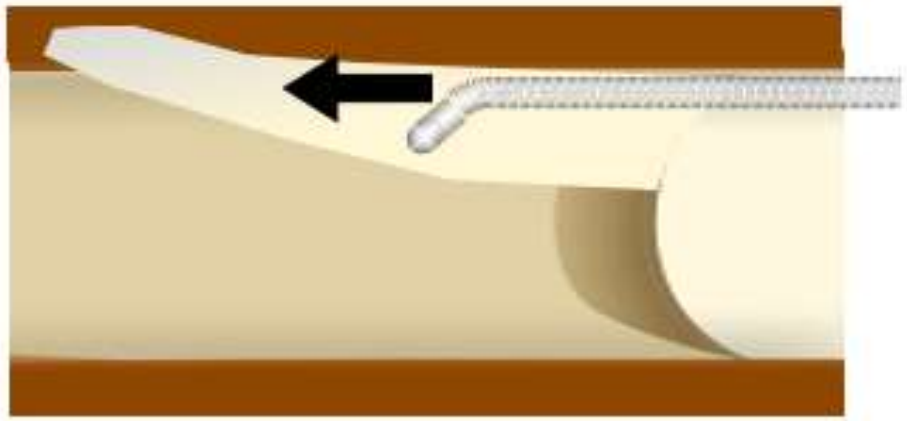


In a large space, tip deflection does not occur.

After whipping of GW…



After rotation of the GW tip by whipping, a large space (semilunar space) is created



In a large space, tip deflection does not occur.

→Make 2nd curve
→a larger semilunar space

Various factors affect tip deflection

Lesion associated	Tissue hardness
	Tissue homogeneity
	Semilunar space
GW associated	Tip curve
	Penetration efficiency; tip diameter, tip load, coating
	Rigidity gap at GW tip
	Shaft rigidity

- Of course, we would like to control the tip deflection !
- However, it is extremely difficult to predict or control how GW tip deflects.
- Because various factors affect tip deflection, and especially we can not control lesion associated factors.

What are the limitations of the mechanical guidewire

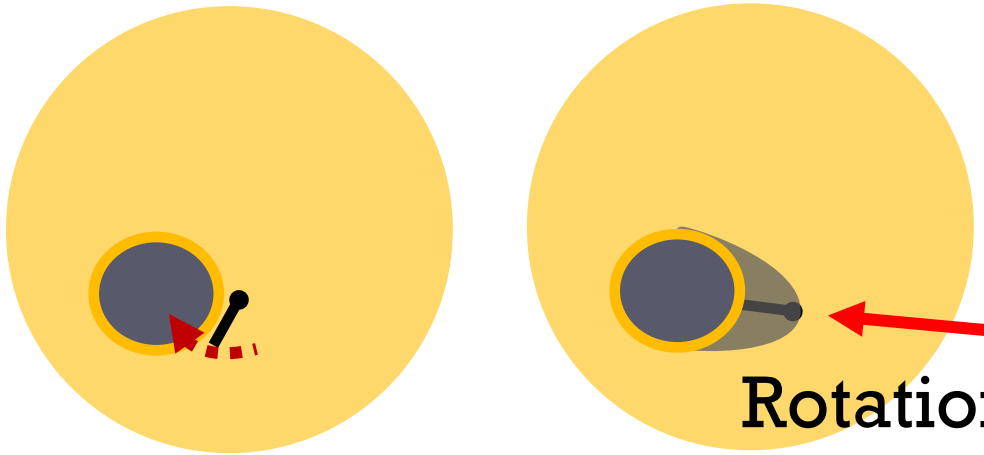
There are some uncontrollable issues for manipulation of the mechanical guidewire

1: Whipping motion

2: Tip deflection

3: Penetration

When the distal cap has membrane (layered structure)



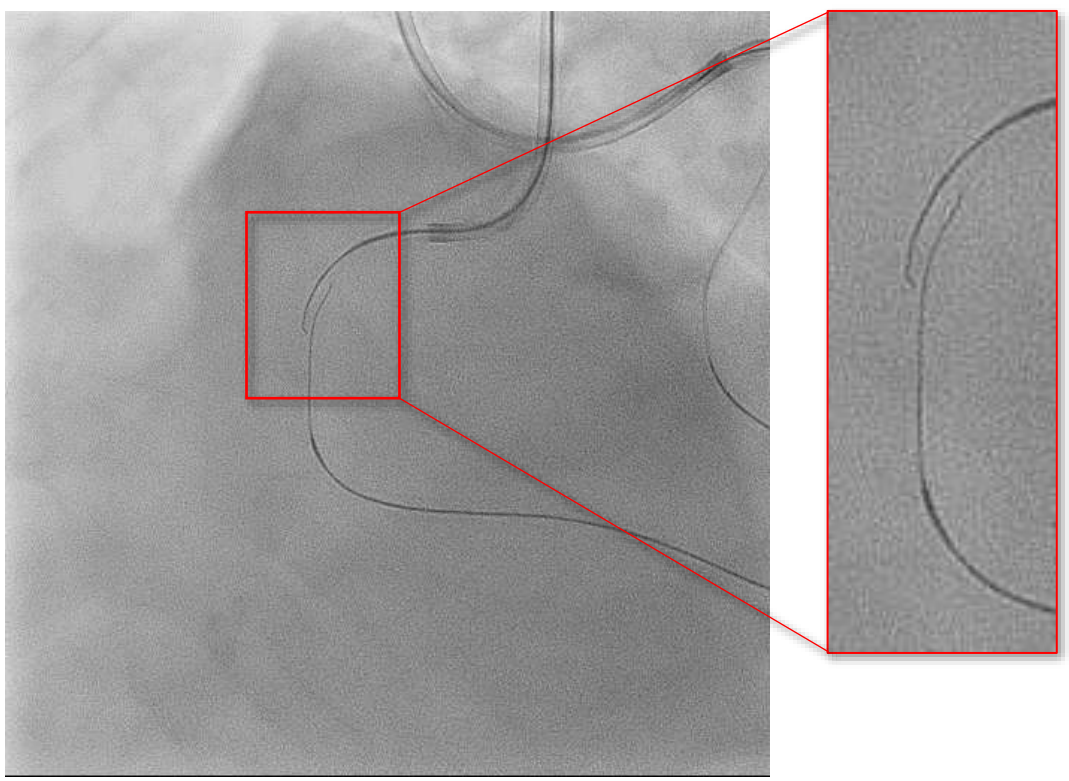
- **Membrane➡ Need of penetration**
- **Avulsion by rotation of GW doesn't work**

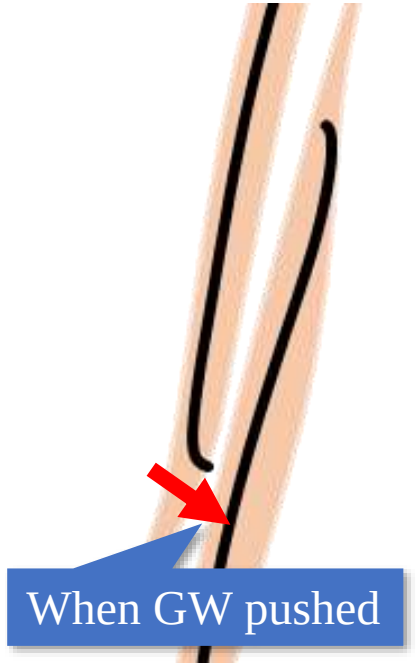
Plane insertion from this side

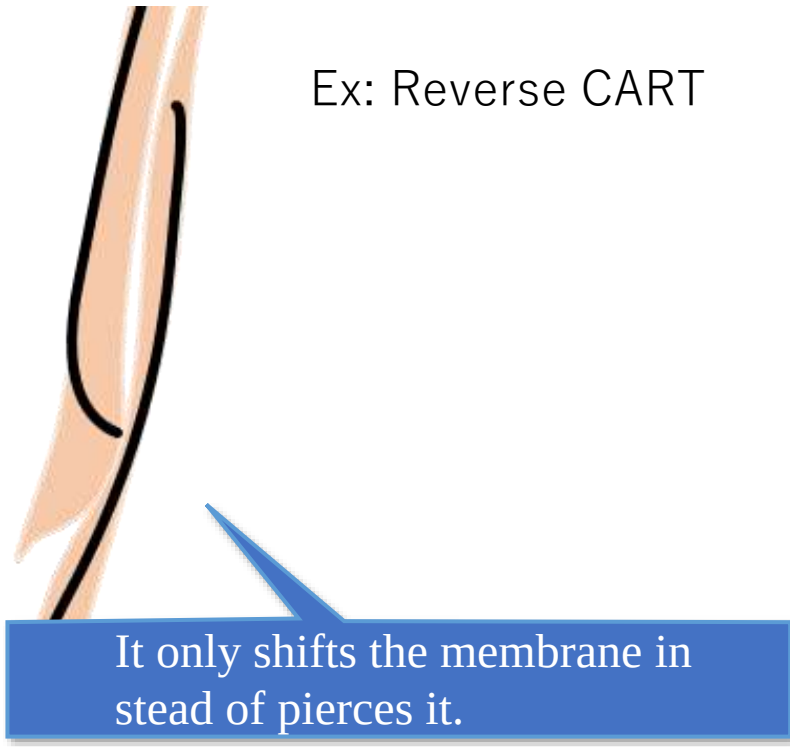
In layered tissues, penetration by intentional tip deflection is required. And intentional penetration requires penetration from a plane perpendicular to the true lumen.

Under such conditions, it is easy to assume that a stiff wire with a high tip load should be used to improve rotation and penetration force, but it is necessary to understand that the dissection cavity is enlarged by the shaft, the bending moment and whipping phenomenon by the tip becomes stronger, and the semilunar pace increases, making tip control more difficult.

Mechanical GW sometimes can not penetrate a membrane

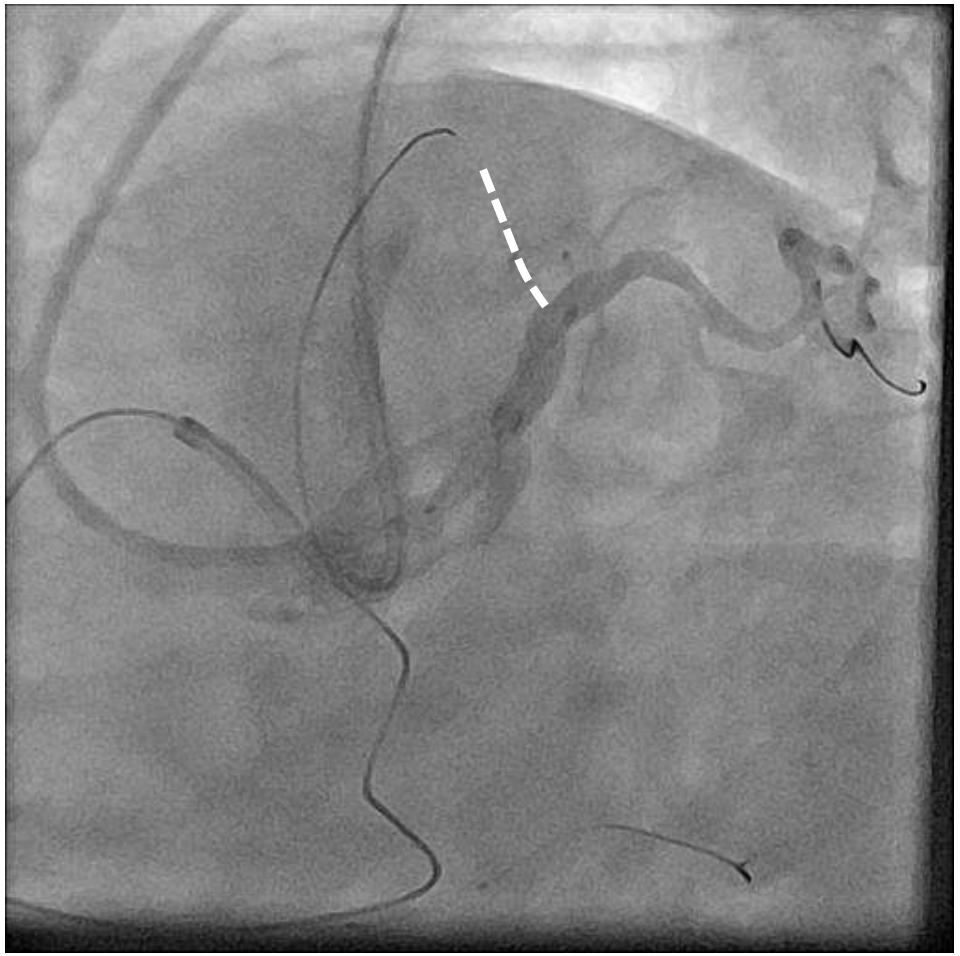




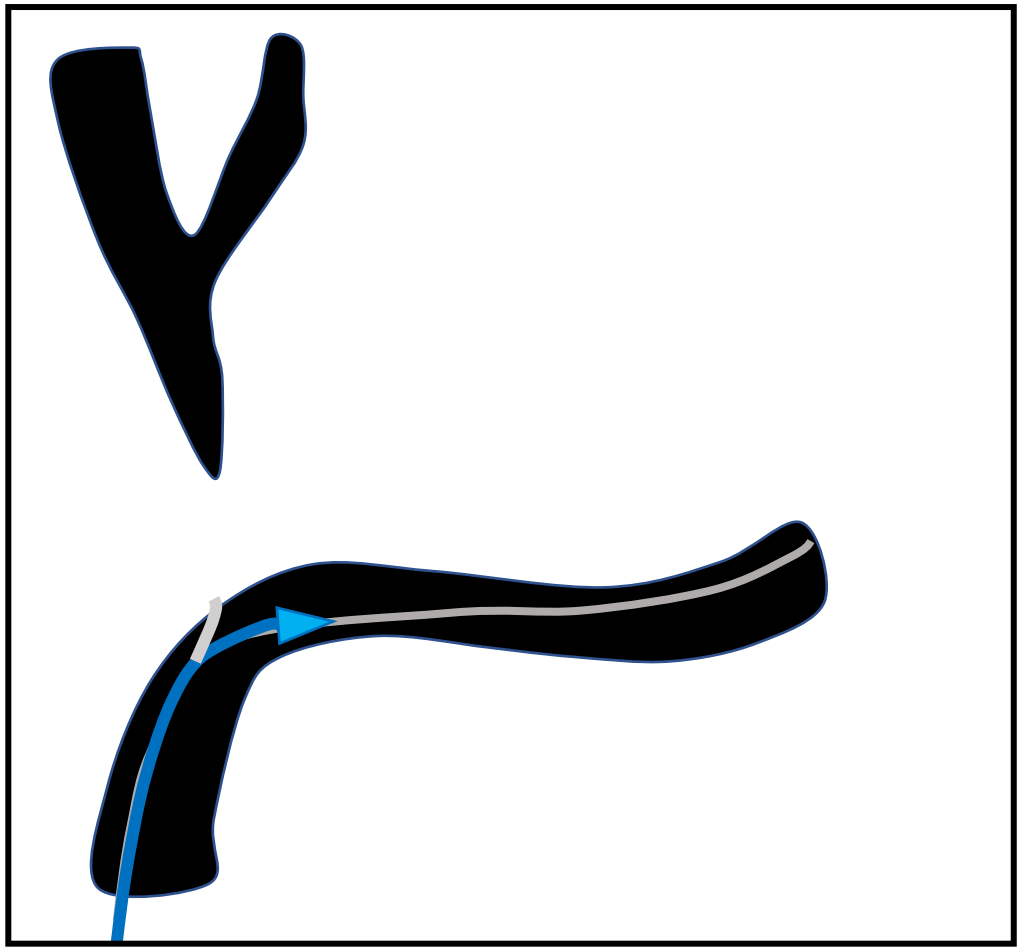


The difficulty of mechanical wire penetration through layered tissue can be easily understood by considering the situation of Retrograde wiring. As you can see, even if the ante and retro wires are close to each other, it is not easy to create a connection. To overcome this situation, it is necessary to add a large 2nd curve to fix the tip with resistance from the wall and generate strong deflection. However, this 2nd curve makes directional control difficult and can also lead to the enlargement of the dissection cavity. This is the principal limitation of mechanical wire manipulation.

Mechanical GW sometimes can not penetrate a membrane



Ex: LADjp CTO



Furthermore, it can be also very difficult to penetrate hard tissue at an angle from a large space, even with a wire with high penetration force.

What are the limitations of the mechanical guidewire

There are some uncontrollable issues for manipulation of the mechanical guidewire

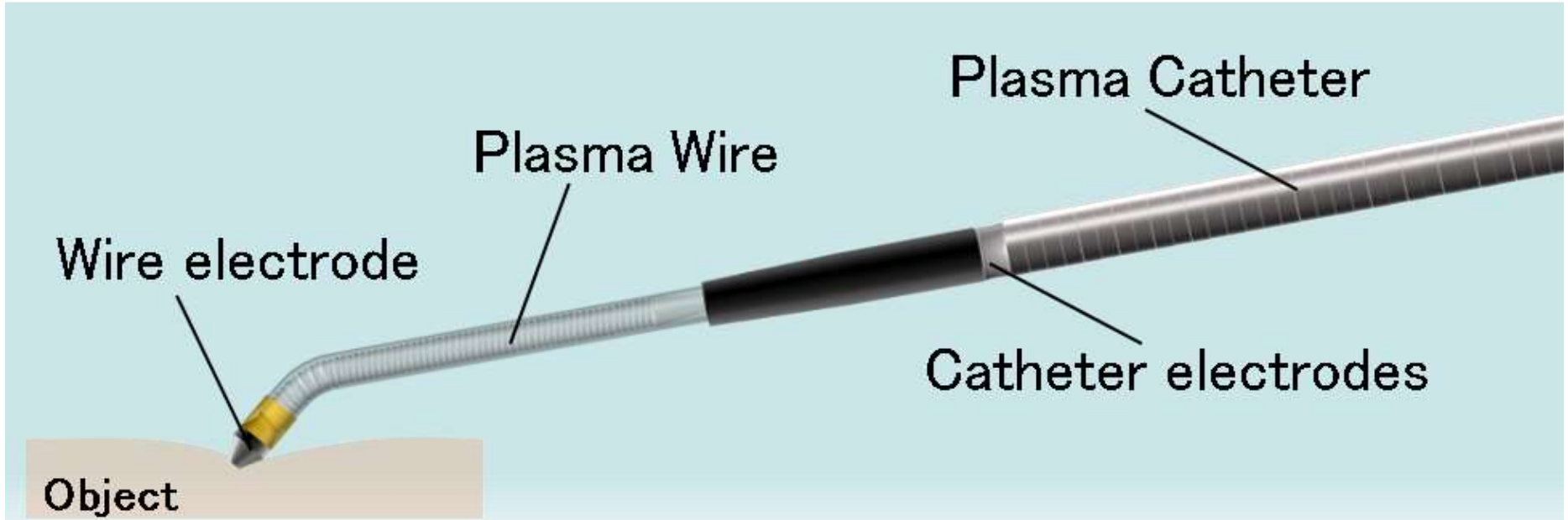
1: Whipping motion

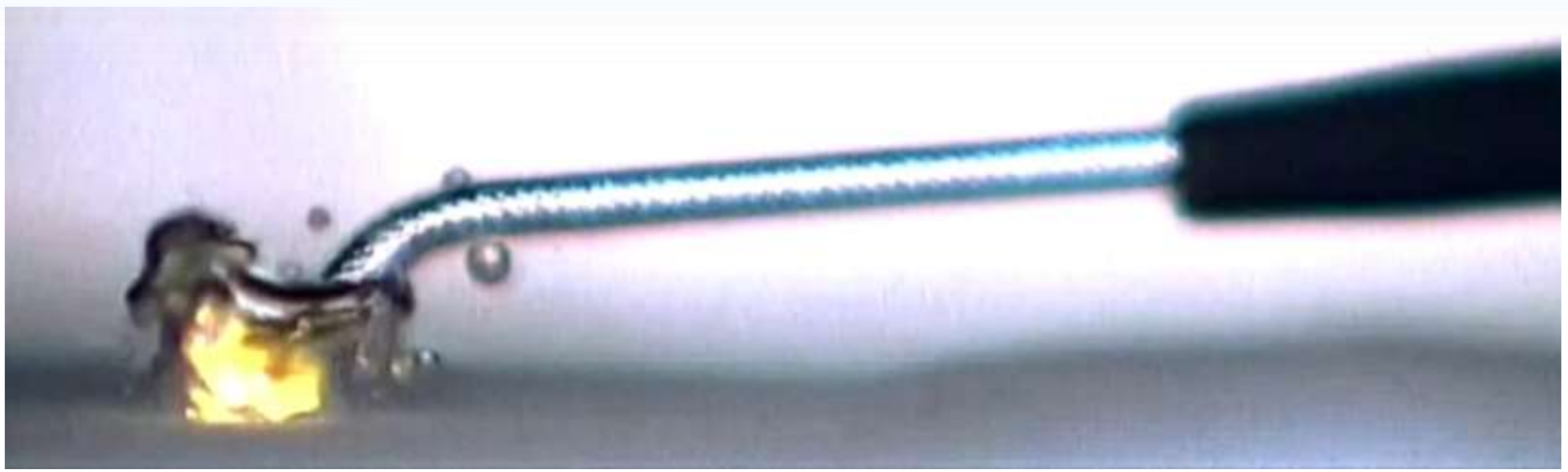
2: Tip deflection

3: Penetration

➡ Once a semilunar space is created, deflection control of the wire is no longer possible and wire manipulation becomes difficult. In addition, it is difficult to penetrate the wire through the space (or from where the space exists).

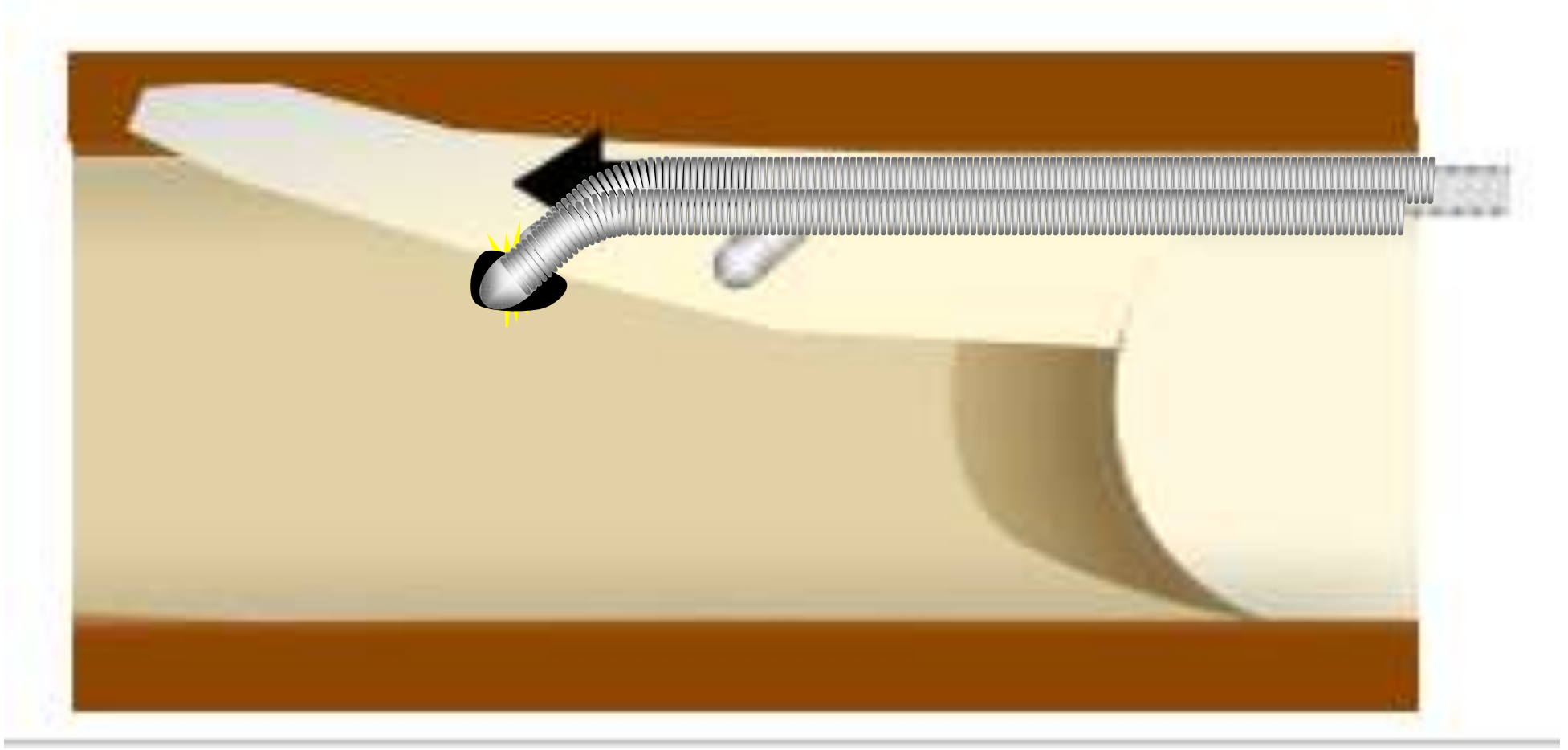
Plasma-Mediated Ablation System

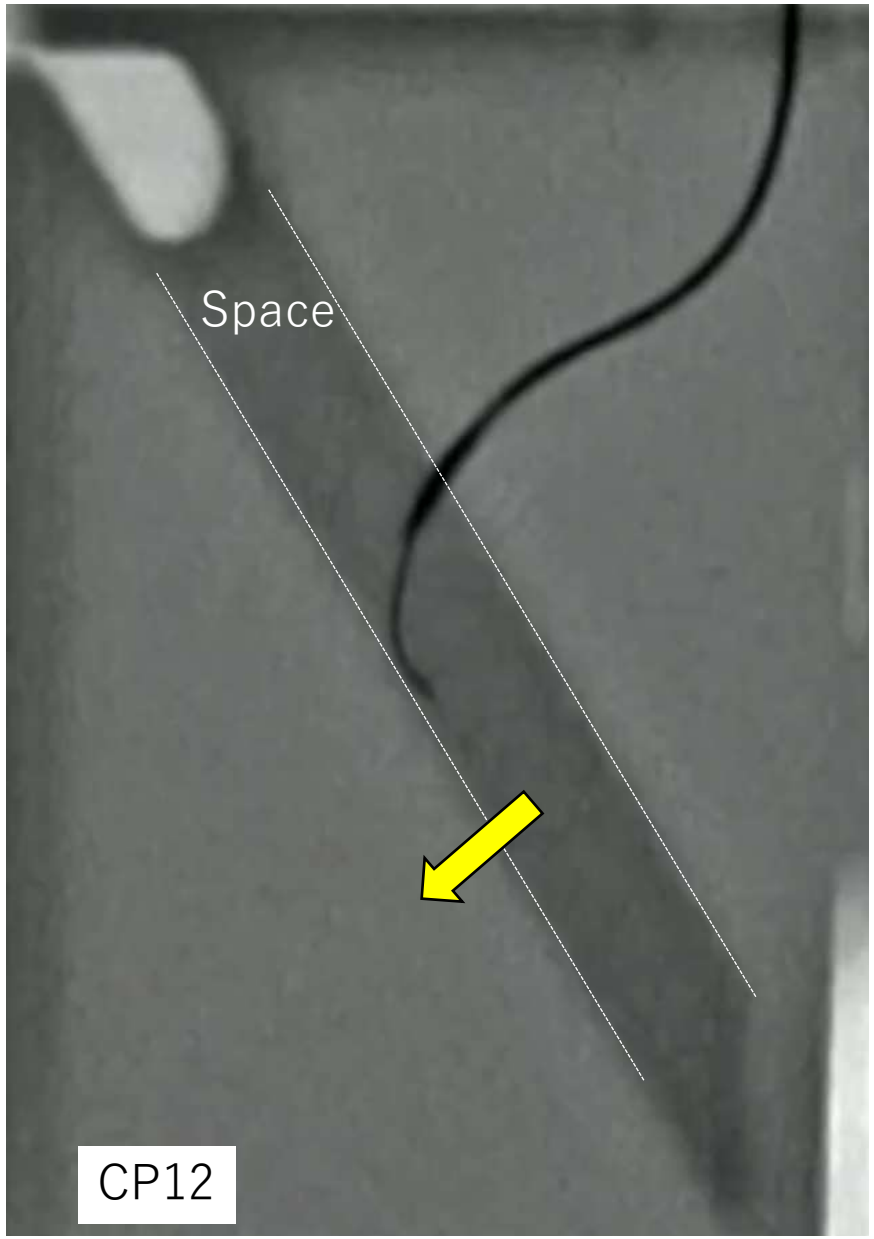


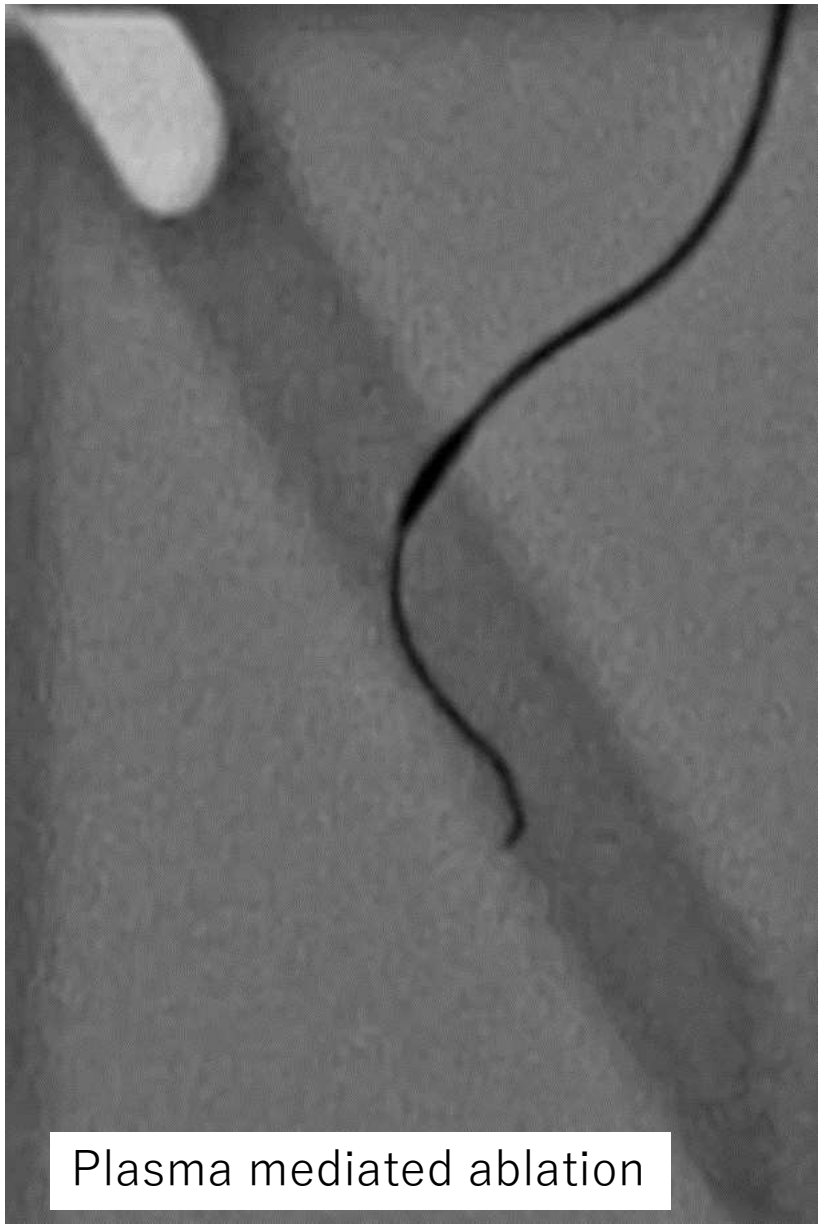


Plasmawire can be penetrated with the tip of the Plasmawire in contact with the target.

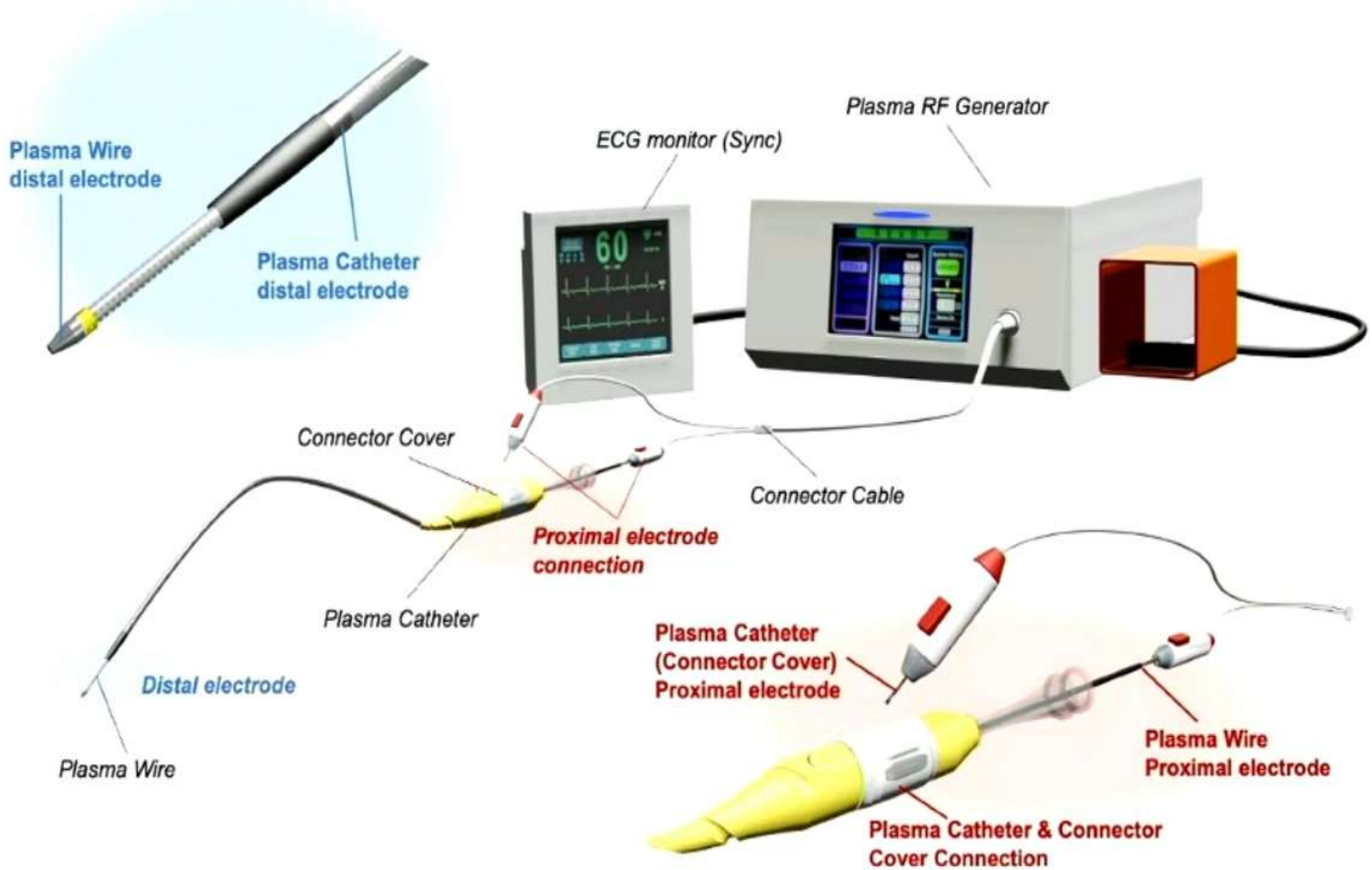
Plasma-Mediated Ablation System



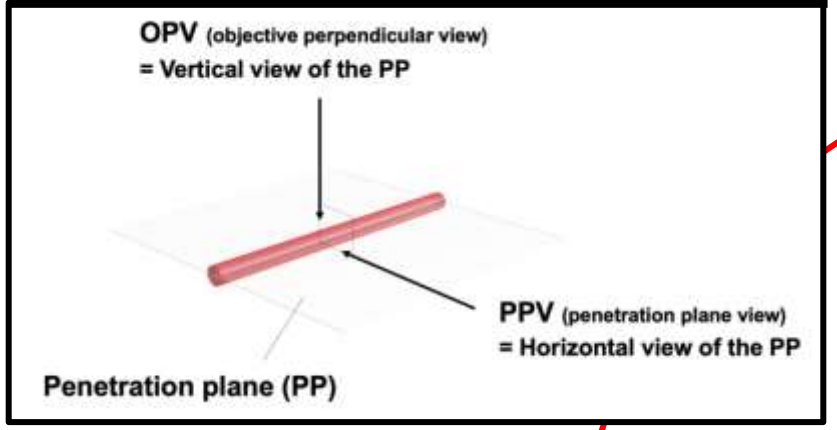

Space
CP12


Plasma mediated ablation

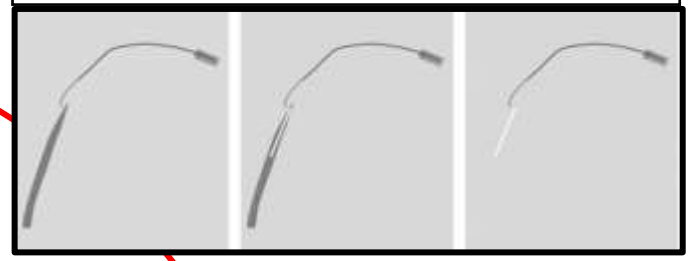
Plasma mediated ablation (PMA) system



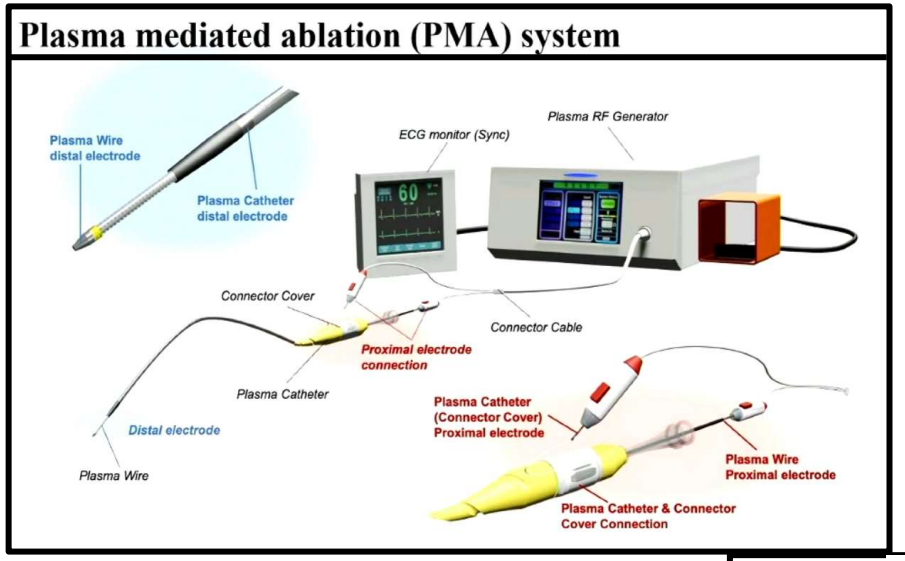
Penetration Plane method



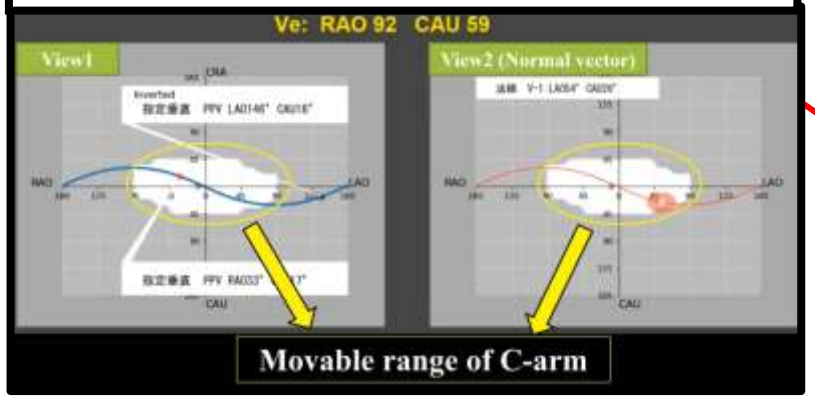
Distal true lumen mapping



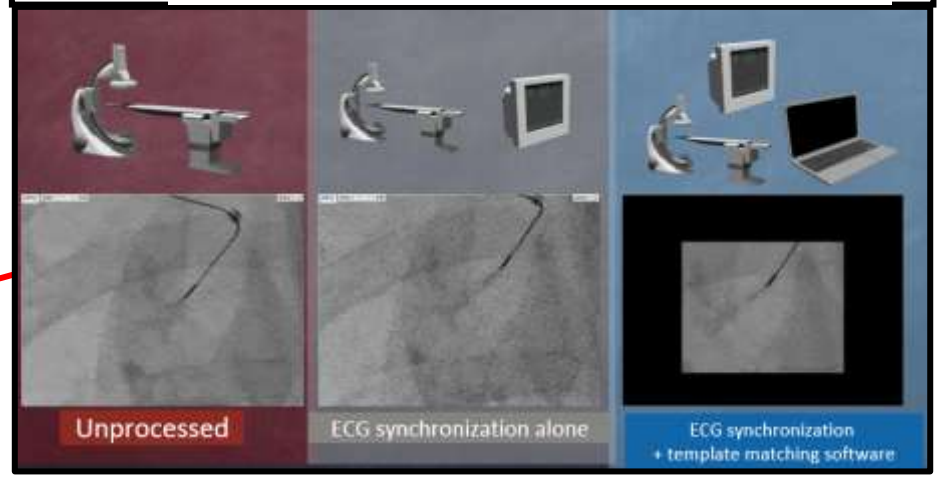
Plasma mediated ablation (PMA) system



Axis-vector analysis software



ECG-synchronized fluoroscopy



Plasma-Mediated Ablation System

- Although mechanical wires are improving day by day, there are still limitations that have yet to be resolved.
- Plasma ablation system and the methodologies (PP method), devices (ex. ECG-gated fluoroscopy)to use them safely and effectively could solve them.