

Structural Overview of Angiographic Catheter and Guiding Catheter Commonly Used in Percutaneous Coronary Intervention

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Abstract: Angiographic catheters and Guiding catheters play an important role in percutaneous coronary intervention. The structure and performance of the Angiographic catheter determine whether the contrast agent can be successfully injected into the target vessel, thus providing a preliminary basis for the diagnosis of the disease. Guiding catheter provides access for related devices and determines whether percutaneous coronary intervention can be carried out smoothly. The structure of the angiographic catheter and the guiding catheter are described in detail. The angiographic catheter consists of hub, relief, body, bridge section and soft tip. The structure of the guiding catheter includes hub, relief, pushing section, kink-resistance section, coaxial section and a soft tip. The materials and processing technology involved in each component of angiographic catheter and guiding catheter are described and analyzed in detail.

Keywords: medical device, percutaneous coronary intervention, angiographic catheter, guiding catheter

1. Overview

The Report on Cardiovascular Health and Diseases in China 2019 released by the National Cardiovascular Disease Center that the number of PCI patients in Mainland China in 2018 was 915,256, with a year-on-year increase of 21.53%. In 2018, the average number of patients per million population with coronary heart disease in China was 651, and the average number of stent implantation was 1.46 in terms of coronary disease patient Based on the above data, both the total usage and the growth of related PCI in mainland China have reached a dramatic amount. A successful PCI operation involves a variety of consumables, which are mainly divided into the following categories: catheter, guide wire, stent and accessories. This article will focus on catheters and describe catheter structures commonly used in coronary intervention. This article will concentrate the following two types of catheters commonly used in PCI: Angiographic catheter and guiding catheter.

2. Angiographic catheter

Coronary angiography is the golden standard for the diagnosis of coronary heart disease. The procedure is to puncture the angiographic catheter through the femoral artery of the thigh or the radial artery of the upper limb and insert it into the coronary artery ostium. The contrast agent is selectively injected into the coronary artery and the development process is recorded to determine whether the coronary artery has blocked or not. At present, the angiographic catheter market in mainland China is dominated by Terumo from Japan. Angiographic catheter is mainly composed of hub, relief, body, bridge and soft tip. The schematic drawing of the angiographic catheter is shown in Figure 1.



Figure 1. Schematic drawing of angiographic catheter

2.1 Hub of angiographic catheter

The hub is possibly made of polycarbonate (PC), thermoplastic polyurethane (TPU) or polyether block amides for extreme performance (Pebax). The hub possesses a standard female luer-locker in order to connect a Y valve or manifolds with a male luer-locker. The side plane of catheter hub can be printed or marked by laser to convey information such as the outer diameter of the angiographic catheter, the maximum diameter of the compatible guide wire and the shape of the catheter to the doctor. The hub is able to adopt the double-wing mode to facilitate the doctor to rotate the angiographic catheter so that more smoothly to arrive at the target coronary ostium and complete coronary angiography.

2.2 Relief

There is an abrupt transmission between body and hub so that there is a risk which means kink during operation or transportation. As a result to possibly inflect the patient health and scrap the product. Therefore, the relief becomes a necessary part for catheter. The function of relief is to buffer the abrupt transition between the hub and the body in order to eliminate the risk for the operation and product.. The material type of relief can be selected widely, as long as the material is medical grade plastic and material is kind of medium and high shore-hardness. For example, high shore-hardness thermoplastic polyurethane (TPU), high shore-hardness polyether block amides extreme performance (Pebax), polyolefin and so on.

2.3 Body

The body is a sandwich composed of outer layer, middle layer and inner layer respectively. Each manufacturer has a different understanding of the body resulting to different type of angiographic catheter body Furthermore, different hand-feeling conveyed to operator.

2.3.1 Inner layer

The inner layer of the body can be prepared with pure material, such as polytetrafluoroethylene (PTFE), polyether block polyamide (Pebax) and so on; It can also be produced by compounds, such as Nylon and artificial rubber, mixed with a certain ratio of colorant, with a certain ratio of barium sulfate (BaSO_4), with a certain ratio of bismuth trioxide (Bi_2O_3), with a certain ratio of bismuth subcarbonate ($(\text{BiO})_2\text{CO}_3$), and with a certain ratio of bismuth chloride oxide (BiClO) and so on.

2.3.2 Middle layer

The middle layer of the body is made of metal braided structure, and the material used tends to be stainless steel. Stainless steel is not only affordable, but also it can provide better torque and pushability for the product compared to the pure polymer. For multi-purpose catheters (both suitable for left and right coronary by one catheter), it can reach the targeted position more quickly and accurately.

2.3.3 Outer layer

The outer layer of the body are made of polymeric compound because it is necessary that the catheter is visible under X-ray by naked eyes during interventional operation, plenty of manufacturers add inorganic powder to the outer jacket to make the catheter visible under x-rays during surgery. The added inorganic powder is the same as the inner layer. Because the catheter needs unique identification in vitro, especially during operation, which is convenient for doctors and nurses to identify the catheters that they desire. Thus, manufacturers will add the corresponding colorant to complete the coloring of the whole catheter.

2.4 Bridge segment

At present, the main angiographic catheter on the market is equipped with a bridge section, which is defined as a tubing between the body and the soft tip. The bridge section is mostly a piece of single lumen extrusion tubing with moderate hardness. This single lumen tubing is prepared by conventional extruder without metal braided layer. Two processes are commonly used to connect the bridge segment to the body and soft tip. Firstly, the bridge segment is connected to the body and the soft tip by heating. Secondly, through continuous extrusion process, the bridge section is extruded accompanying with the body, and then the soft tip is fused with the combination of the bridge section and the body.

2.5 Soft tip

The catheter tip must be soft enough to protect the inner wall of the vessel from avoiding to be scratched because the catheter needs to pass through the radial, femoral or branchial artery to reach the ascending aorta and engage in the left and right coronary ostium. According to YY 0285.1-2017 Intravascular catheters- Sterile and single-use catheters-Part 1: General requirements-4.12: The distal tip shall be smooth, rounded, tapered or similarly finished in order to minimize trauma to vessels during use, In terms of the international standard described above, the soft tip of the catheter is treated accordingly

to protect the vessels during use

3. Guiding catheter

Guiding catheter, as the delivery channel of coronary interventional medical devices such as stent, balloon catheter, guiding wire and so on, is very important to the success of surgery. The guiding catheter not only acts as a delivery channel, but also is able to monitor blood pressure and inject contrast agents. At present, the guiding catheter market in mainland China is dominated by Medtronic and Cordis which both from US. Although the general structure of the guiding catheter is similar to angiographic catheter, However, it is more emphasized that the precision of size and more inner diameter with the same outer diameter. To pursuit inner diameter with the same out diameter without sacrifice relative character is most challenging target for the manufacture. The guiding catheter is composed of a hub, a relief, a pushing section, a kink-resistance section, a coaxial section and a soft tip. The schematic drawing of the guiding catheter is shown in Figure 2.



Figure 2. Schematic drawing of guiding catheter

3.1 Guiding catheter hub

The guiding catheter hub is similar to the angiographic catheter and is mostly made of polycarbonate (PC), thermoplastic polyurethane (TPU) or polyether block polyamide (Pebax). The guiding catheter also has a standard female luer-lock to connect Y valve. Neither Medtronic nor Cordis labels any information on the catheter hub. Medtronic uses catheter hubs of different colors to correspond to catheters with different outer diameters (5Fr, 6Fr, 7Fr, 8Fr).

3.2 Relief

The relief of the guiding catheter is similar to angiographic catheter and is used to cushion the abrupt transition between the catheter hub and the body. To prevent catheter kink. Relief can choose medium or high shore-hardness single lumen extrusion tubing, low shore-hardness thermoplastic elastomer, heat shrinkable tubing and so on. Comparing to other parts, Relief is not a key for the entire product. Both Medtronic and Cordis label the product model number and outer diameter on the white Relief.

3.3 Pushing section

The pushing section of the guiding catheter consists of three layers, namely the inner layer, the middle layer and the outer layer. Cordis chooses teflon material as the pushing section inner layer, while Medtronic chooses fluorine-free material as the pushing section inner layer. The choice of inner layer material directly determines the smoothness of other interventional medical devices passing through the guiding catheter. If the inner material is not smooth enough, it can show the doctor a "pebble" effect. At present, polytetrafluoroethylene is the lowest friction coefficient in the mass production of polymer materials. The inner layer of teflon makes the lumen of the catheter smoother and delivering other medical device more smoother. The disadvantage of choosing polytetrafluoroethylene is that polytetrafluoroethylene is so expensive the manufacturing process is difficult, furthermore, polytetrafluoroethylene, as a non-stick material, is challenging to bond with the traditional outer layer material of the guiding catheter.

The intermediate layer of the guiding catheter is made of metallic mesh. The guiding catheter of Medtronic Launcher is made of stainless steel flat wire, which is braided with one wire goes over two wires up and down. The size of the braiding wire is 0.0015"×0.005". The advantage of using flat wire with 1 over 2 is that the wall thickness can be relatively reduced compared to round wire, leaving enough space for larger inner diameter and smaller outer diameter, which is the key

performance for an excellent guiding catheter The Cordis Vista Brite Tip guiding catheter is made of stainless steel with one round wire and one flat wire diameter of 0.066" and dimensions of 0.0012"×0.0032". One round wire and one flat wire, one goes over one up and down. Compared with entire flat braiding structure, the mixed round and flat braided provides better support. The braided mesh of Cordis uses spot welding to weld round wire and flat wire together, so that during the production of the catheter, the braided mesh will not burst wire and pierce the outer surface of the catheter, which will cause the risk of scratching blood vessels, which is unacceptable.

The jacket of the guiding catheter is usually X-ray - visible polymer composite material. The base material is polyether block polyamide and thermoplastic polyurethane with suitable hardness. Different manufacturers have different understandings of the outer layer of the guiding catheter. The outer surface of the guiding catheter produced by Medtronic is matte and has obvious regular texture for the feeling The Cordis Vista Brite Tip has a glossy exterior and feels smooth without any particle. In the author's opinion, when the texture with obvious regularity contacts the sheath internal surface and the inner wall of blood vessel, it belongs to point contact rather than surface contact, which can reduce the friction between the catheter, the sheath internal surface and the inner wall of blood vessel. The guiding catheter with bright surface is easy to produce mirror effect, which makes the friction between the catheter and sheath and the inner wall of blood vessel relatively larger.

3.4 Kink-resistance section and coaxial section

The current official definition of kink-resistance section and coaxial section is not very clear. In the author's opinion, kink-resistance section is a buffer between the body and the coaxial section, and coaxial section is a soft bridge between the distal tip and the kink-resistance section. The main purpose of the kink-resistance section is to cushion the abrupt transition between the body and the coaxial section and reduce the risk of kink the catheter from the hard section to the relative soft section. The purpose of coaxial segment is mainly to align the catheter distal and coronary artery's center line, so that the guide wire, balloon catheter, stent and other medical devices can smoothly enter the coronary artery from the catheter lumen to the lesion. Therefore, the overall hardness of the coaxial section should be soft enough. The international dominating manufacturing process is not to change the material and thickness of the inner layer, by changing the middle braided layer and outer material to adjust the hardness of the kink-resistance section and coaxial section.

Middle braided layer hardness can be achieved by adjusting PPI or size of braiding wire or shape of braiding wire. The hardness of outer jacket can be adjusted by the hardness of the outer compound. Tungsten fillers are well-known to be more visible under X-ray than bismuth salts and barium sulfate. Medtronic uses tungsten-containing materials in the coaxial segment for excellent visibility during operation. Thermal shrinkage process is common used to form the outer jacket of the kink-resistance and coaxial section. This process is easy to operate and the hardness of the kink-resistance and coaxial section can be tuned by changing the materials of single lumen tubing.

3.5 Soft tip

A soft tip is usually defined as a very soft tubing at the distal end of a guiding catheter. The soft tip allows the catheter to minimize the risk of damaging the inner wall of the vessel when arriving at coronary ostium, during operation. Soft tip material is always chosen low hardness polyether block polyamide substrate or thermoplastic polyurethane substrate. The guiding catheter of Medtronic Launcher employs relative low visible compound to be the soft tip, Nevertheless, Cordis Vista Brite Tip employs ultra-visible compound to form soft tip. Both approaches are currently accepted by the market. The brightness of soft tip under X-ray mainly depends on the percentage and type of inorganic filler.

4. Conclusion

Both angiographic catheter and guiding catheter are necessarily used in percutaneous coronary intervention The intended use of the angiographic catheter is to inject contrast agent into the targeted vessels, so the tolerance requirement of the lumen is not particularly high. The multifunctional coronary angiographic catheter emphasizes torque control, because one angiographic catheter should be used for both left and right coronary angiography, and adequate torque transmission is required for the angiographic catheter to be rotated from left to right or from right to left coronary artery. Otherwise, the doctor may feel that the catheter is not responsible enough to reach its target. The intended use of the guiding catheter is to provide a channel for balloon catheter, guide wire or other interventional medical device. Therefore, the requirements of the guiding catheter for the lumen are very strict, and it is unacceptable that the relative medical device cannot pass through the guiding catheter's lumen. Guiding catheter emphasizes the larger lumen and thinner wall. The lumen should be as large as possible under the condition that the outer diameter is fixed and the supporting force is sufficient. So as to provide larger access for other devices such as balloon catheters.

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