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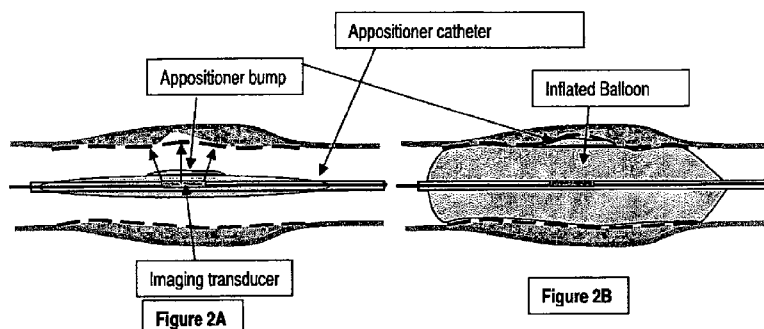
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(54) Title: STENT STRUT APPOSITIONER



(57) Abstract: Devices and procedures for treating malapposed or non apposed stent strut are disclosed. In general, an angioplasty balloon catheter coupled with a uniquely shaped bump is delivered within the stent and positioned to align the bump with the malapposed or non apposed stent strut. The balloon is inflated to drive the bump against the target strut to apposed it properly against the lumen wall.

DESCRIPTION

Stent Strut Appositioner

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Background of Invention:

[001] A stent, metal mesh, is expanded in a narrowed vessel to prop the vessel open to allow blood to flow through. Often, the narrowing is caused by plaque deposit that can be rough or uneven resulting in a rough lumen. Oftentimes after the stent is expanded the struts on the stent may not be able to conform to the pits or grooves on the lumen surface and result in a gap between lumen surface and the stent strut (fig.1). This is called non apposed or malapposed stent strut. This gap traps blood into a stagnant or unsteady state resulting in thrombus formation. The phenomenon is more likely to occur with drug eluting stents (DES) because of lack of tissue healing over the strut or tissue eroding from the drug. Thrombus formation can lead to rapid occlusion of the vessel and can cause major complication or death. There is a need for a means to focally push the stent strut against the vessel luminal surface to eliminate the gap that leads to thrombosis.

Description of Drawings:

- [002] Figure1 illustrates the problem of the stent not apposing against the lumen surface leaving a gap.
- [003] Figure 2 illustrates the procedure of delivering the Appositioner Catheter and activating the mechanism to fix the apposition problem with the stent strut. Also show is the design/construction of the Appositioner Catheter and system.
- [004] Figure 3 shows a method for forming the Appositioner Balloon.

Description of Invention:**Basic Concept:**

- [005] The invention is an elongated device like an angioplasty balloon catheter (Appositioner Catheter) with a special bump on the surface designed to engage and push the non apposed/ malapposed stent strut against the vessel wall focally.
- [006] The preferred method for effecting apposition of a non apposed/malapposed strut (NA strut) against lumen surface is to use a balloon catheter with a bump (Appositioner) for pushing NA strut against the vessel wall (fig.2). The balloon can be formed so that a portion of the surface protrudes radially beyond the surface of the rest of the balloon surface (Fig.3). The Appositioner can also be bonded onto the surface of the balloon so that it protrudes beyond the surface. It is preferred that there is direct visualization means (optical coherence tomography, fiberscope, or intravascular ultrasound) coupled with the catheter to visualize where the NA strut is and allow the physician to direct the Appositioner against the NA strut to push the strut against the lumen surface.

Procedure:

- [007] The Appositioner Catheter with the balloon collapsed and folded is advanced over the guidewire until it crosses a stent deployed in a lesion so that it is distal to the lesion. The wire is exchanged for an imaging wire such as the optical coherence tomography wire (OCT). An occluder balloon is inflated to occlude blood. Saline is used to flush out the blood around the OCT visualization field. The OCT is pulled back to identify the first NA strut (most distal). The Appositioner Catheter is pulled back axially until the Appositioner is lined up with the NA strut (same transverse plane and can be both visible with OCT simultaneously). The balloon is then deployed by inflating at low pressure [1-3 atmospheres (ATM)]. The catheter is then rotated so that the Appositioner is radially lined up with the NA strut. The balloon is further inflated to push the Appositioner up to the NA strut (4-6 ATM). Small adjustments can be made by translating the catheter axially or rotating the catheter to perfectly line up the Appositioner with the NA strut. Then the balloon can be inflated fully to push the strut against the vessel wall (7-14 ATM). The balloon is then deflated and pulled back with the imaging wire to treat the next NA strut.

Detailed Description of Device:

[008] The Appositioner is shaped like a mound with a flat top or slightly concave or saddle shaped top when fully deployed and stands protrudes radially outward from the surface of inflated balloon. It is preferably made of optically clear material [nylon, polyethylene, fluoropolymer, polyether block amide (Pebax), polyurethane, silicone, polycarbonate or polyethylene terephthalate (PET)]. It is .002"-.040" in height, .003"-.040" wide, and .003"-.040" length. It is preferably radioopaque (fill with barium sulfate or bismuth) and/or has metal (stainless steel, platinum, tungsten, iridium, gold) embedded or attached to the top. It can be a molded or machined piece that is bonded to the balloon (heat weld, glued, snap fitted, sutured). It can be molded into the balloon material. It can also be part of the balloon that is shaped such that the balloon bulges out more to the shape of the Appositioner under pressure. In this case the balloon is made by placing a polymer tube (nylon 12) in a mold (glass or metal) with the final shape of the balloon with a cavity in a spot with the shape of the Appositioner (Fig.3). The tube is pressurized with heat to expand the balloon tube to the shape of the mold and further heated (300-500 degrees F) for a duration of time. The mold is cooled while maintaining pressure. Then the balloon shape is set with the Appositioner protruded at a spot.

[009] The balloon is oblong in shape and is 3-8 mm long and ranges in diameters from 2-10 mm in diameter depending on the vessel diameter fully inflated. For coronary arteries, it is preferably 2-4 mm in diameter and 3-6 mm in length. It is tapered on the proximal and distal end to bond (heat weld or glued) to the catheter. The balloon is .0005-.008" thick (preferably .001" thick). The material is nylon, polyethylene, Pebax, PET, silicone, polyurethane or a combination thereof. Preferably it is nylon or Pebax.

[0010] The catheter shaft is a tube with outer diameter of .5mm to 2mm and has balloon inflation port near the tip. The inner tube within the outer tube has inner diameter of .014"-.040" and accommodates a guidewire. It is optically clear at tip to allow imaging device to see through. The shaft has a metal braid (stainless steel) or metal coil embedded to provide

torsional strength and stiffness and yet remain flexible in bending to traverse easily through tortuosity in the vasculature.

[0011] The catheter may have a proximal balloon to occlude blood and a flush port to flush blood distal to the proximal balloon to clear out blood for visualization such as OCT.

[0012] Other ways to effect apposition include having an arm that protrude out the side port of the catheter to push on the strut or a basket with series of longitudinal tines that can be expanded. A tine can have the Appositioner on the outer most point of the arch. The catheter can also flex by pulling on a side tendon to point the tip towards the NA strut and push it against the vessel wall.

CLAIMS

What is claimed are:

1. A device for focally pushing the stent strut against the vessel wall comprising:
An elongated member with proximal and distal end;
a balloon on a catheter;
a bump configured for pushing on stent strut protruding out from outer surface of the balloon
2. The device as in 1 is coupled with a direct visualization means
3. The visualization means as in 2 is selected from intravascular ultrasound, fiberoptics, and optical coherence tomography
4. The device as in 1 is configured to allow the visualization means to slide axially relative to the device
5. The device as in 1 has one or more helical metal coils wound around the shaft
6. The device as in 1 is flexible in bending but is stiff in rotation
7. The device as in 1 is a catheter with shaft diameter of .5-2mm
8. The device as in 1 has a working length of 90cm-150cm
9. The balloon material as in 1 is selected from nylon, Pebax, PET, silicone, polyethylene, or fluoropolymer
10. The balloon as in 1 has inflated diameter of 2-10mm and 3-8mm in length, and has wall thickness of .0005"- .008"
11. The balloon as in 1 has uninflated diameter of .5-2mm
12. The balloon as in 1 has at least one helically wound metal coil on the wall
13. The catheter as in 1 comprises an expandable element beyond the said balloon for occluding blood flow
14. The catheter as in 1 has a flush port approximating balloon configured for delivering fluid from outside body to space around balloon
15. The bump as in 1 is located near the midpoint between the ends of the balloon
16. The bump as in 1 is concave or saddle shaped on top surface
17. The bump as in 1 is flat on the top surface

18. The bump as in 1 is larger in cross section at the junction with balloon than that which is farthest from surface of balloon
19. The bump as in 1, is part of the balloon and bulges out when the balloon is inflated
20. The bump as in 18 is a separate component bonded to the balloon
21. The bump as in 18 is optically translucent or clear
22. The bump as in 18 is partially transparent to the direct visualization means
23. The bump as in 18 has radioopaque markers approximating its surface
24. The bump as in 18 is stiffer than the balloon
25. The bump as in 18 is selected from nylon, Pebax, PET, and polyurethane
26. The bump as in 18 has metal embedded in the wall
27. The bump as in 18 has metal attached to the wall
28. The bump as in 18 protrudes outward from in balloon surface by .1-5mm
29. The bump as in 18 is molded or machined before attaching to the balloon
30. The bump as in 18 is glued to the balloon
31. The bump as in 18 is heat welded to the balloon
32. The bump as in 18 is formed onto the balloon
33. A method for focally pushing a stent strut against the vessel wall comprising the steps of:
placing a balloon with a bump near a strut that is not apposed against vessel wall;
inflating the balloon;
deflating the balloon;
34. A method as in 33 wherein a direct visualization means is used to visualize the positioning of the bump relative to the stent strut
35. The method as in 34 wherein the direct visualization means is selected from optical coherence tomography, angioscopy, and intravascular ultrasound

Figures

