FIGURE 12

Abstract: The present invention relates to a proximal anastomosis device (1) which enables to perform proximal anastomoses to be performed on the ascending aorta (A) by providing bloodless area required without using side clamp in coronary by-pass surgery, essentially comprising a catheter (2) which has a hollow cylindrical body, a balloon (2.2) which is present on the body in a deflated form such that it will surround a part of the body at the distal end (2.1) of the catheter (2) close to the aorta (A), which enables the blood leakage from the aorta (A) to the outside to be eliminated by fitting completely on the aorta (A) wall by means of its flexible edges when it is inflated, at least one mouth (2.4) which is located at the proximal end (2.3) of the catheter (2) far from the aorta (A), and which provides an opening for inflating the deflated balloon (2.2) and deflecting the related balloon (2.2) which is inflated, a carrier trochar (3) which has a hollow cylindrical body, the end of which close to the (A) aorta is sharp, which has a lumen in a diameter suitable for carrying deflated balloon (2.2) catheter (2) therein, and which enables to place the catheter (2) inside the aorta (A) after aorta (A) puncture, a punch (4) which is comprised of two separate semi-cylinders and which is attached to the catheter (2) body by connecting the related semi-cylinders, at least one blade (4.3) which is present on the surface of the punch (4) facing the aorta (A), and the diameter of which determines the diameter of the aortotomy to be opened.
DESCRIPTION

A MANUAL PROXIMAL ANASTOMOSE DEVICE FOR CORONARY BYPASS SURGERY

Field of the Invention

The present invention relates to a device for medical use which allows performing proximal anastomose by providing required bloodless operation area using manual stitching method without putting side clamp to the aorta in coronary bypass surgery.

Background of the Invention

In coronary bypass operations, the process of attaching saphena graft to the ascending aorta by using suitable stitching materials is called proximal anastomose. In order to perform proximal anastomose or anastomoses, a hole in suitable diameter should be made on the aorta. Since the aorta is filled with high pressurized blood inside by its nature; if the appropriate procedures are not applied, the operation field is filled with blood and it will not be possible to perform anastomose since this results in obscuring the field of view. For this reason, bloodless operation field should be provided. With this purpose, one of the most frequently used technique is to place side clamp to the side of aorta where the anastomose is planned to be performed. Although the clamp application is one of the most common and practical techniques, it also brings several complication risks. Injury or dissection of aorta, plaque emboli from aorta (in an extent that can cause cerebrovascular ischemic events) are among possible complications. For this reason, in order to perform proximal anastomose without using side clamp various products have been developed in the world, however due to the cost and the technical difficulties in application and the complications experienced, the
related products today have not found wide field of use and have not been devices of daily practice.

There are various products developed with this purpose and shortly called as "Proximal Anastomose Devices". These products are essentially classified in two titles, namely "Automatic Proximal Anastomose Devices" and "Manual Proximal Anastomose Devices".

The main difference of the Manual Proximal Anastomose Devices from the Automatic Proximal Anastomose Devices is that it allows the surgeon to perform manual anastomose of the graft by using conventional suture materials. Being different from Automatic Proximal Anastomose Devices, this enables the angle between the graft and the aorta to be adjusted properly according to the surgeon's preference and allows the surgeon to give the desired form to the anastomose and apply the anastomose technique which he is used to perform.

There are two products classified and produced under the title of Manual Proximal Anastomose Devices. The first one of these is the product manufactured by "Mauquet" Company and called as "Heartstring". The most important problem emerging during use of this product is that it cannot provide adequate bloodless area in the anastomose region due to the inadequacy of coaptation of the device to the aorta. The technical reason for not being able to provide the bloodless area required for the operation area is that the inner surface of the aorta is not a flat ground, it is concave due to its cylindrical structure and the whole of the nonflexible flat surface of the product called Heartstring cannot contact the concave aorta inner surface. For this reason, a requirement for using an additional device called blow-mister emerges. Blow-mister device blows air to the anastomose line in order to remove the blood from the area. As a result of this, it has been observed and proven with the studies that the blown air enters into the aorta and reaches the brain via the carotis arteries, creates air emboli and increases
the risk of neurological complications. For this reason, the related device could not find a common field of use.

The other product is the device manufactured by "Novare Surgical System" and called as "Enclose". For this product, in order to provide the bloodless area required for anastomose, the device needs to be placed through a second puncture to the aorta by performing an extra invasive intervention on aorta outside the anastomose area which brings the increased risks of bleeding and dissection. At the same time, the requirement of a second entrance area narrows the area where the anastomose will be performed, and this creates difficulty of use.

The Problems Solved with the Invention

The objective of the present invention is to enable the proximal anastomoses to be performed without using side clamp in Coronary Bypass surgeries. Thus, it is aimed to eliminate the possible complications of using side clamp and to create the opportunity of working with more comfort.

The difference of the invention from other proximal anastomose device are as follows:

- It is easily applicable,
- It can provide a complete bloodless area in the anastomose field with its design,
- It is disposable and it does not require re-sterilization,
- It is applicable to almost every patient and every aorta including structural variations.
- The raw material used for the production of the device is inert (it does not react with the body),
- Especially in aortas with plaque, it eliminates the limitations caused by the use of side clamp and the complications that can occur due to side-clamp application.
Detailed Description of the Invention

A manual proximal anastomose device developed to fulfill the objectives of the present invention is illustrated in the accompanying figures, in which:

Figure 1 is the cross sectional view of the carrier trocar.
Figure 2 is the cross sectional view of the balloon catheter.
Figure 3 is the cross sectional view of the carrier trocar placed into the aorta after aorta puncture.
Figure 4 is the cross section view of the catheter inside the aorta.
Figure 5 is the cross sectional view of the catheter inside the aorta and the carrier trocar separated from the catheter.
Figure 6 is the cross sectional view of the catheter inside the aorta and the inflated balloon at the tip of the catheter.
Figure 7 is the cross sectional view of the catheter on which traction is applied towards the aorta wall from the proximal end in order to provide coaptation.
Figure 8 is the top view of the approximate scale relation of the surface contacting the aorta wall, hollow, catheter and aortotomy while the balloon is inflated.
Figure 9 is the perspective view of the punch.
Figure 10 is the front view of the punch.
Figure 11 is the top view of the punch.
Figure 12 is the cross sectional view of the catheter on which traction is applied towards the aorta wall and punch in form of two separate cylinders to be connected to the catheter.
Figure 13 is the cross sectional view of the punch connected to the catheter and lowered to the aorta wall.
Figure 14 is the cross sectional view of the punch connected to the catheter lifted from the aorta wall.
Figure 15 is the cross sectional view of the punch left the catheter after the aortotomy procedure is completed.

Figure 16 shows the suturing performed between the graft vein to be anastomosed and the aortotomy.

Figure 17 is the front view of the catheter with its balloon deflated inside the aorta.

A reference number is given to each component shown in figures and they are as follows:

1. Proximal anastomose device
2. Catheter
   2.1. Distal end
   2.2. Balloon
   2.3. Proximal end
   2.4. Mouth
3. Carrier trocar
4. Punch
   4.1. Socket clips
   4.2. Tooth clips
   4.3. Blade
A. Aorta
H. Hollow
G. Graft vein
N. Needle
Y. Thread

A manual proximal anastomose device (1), which is to be used by cardiovascular surgery experts in coronary by-pass surgery and enables to perform proximal anastomoses without using aorta (A) side clamp by providing the required bloodless area, essentially comprises
- at least one catheter which has a hollow, preferably cylindrical body,
  - at least one balloon (2.2) which is located on the body of catheter (2) in deflated form in a way that it will surround that part of the related body of the catheter (2) as the distal end (2.1) of the catheter (2) close to the aorta (A), and which enables to eliminate blood leak outwards from the aorta (A) by enabling full contact on inner surface of the aorta (A) with its flexible edges after the traction which will be applied towards the entrance hole of the aorta (A) wall following the inflation inside the aorta (A),
  - at least one mouth (2.4) which is located at the proximal end (2.3) of the catheter (2) far from the aorta (A), and which provides an opening for inflating the deflated balloon (2.2) and deflating the related balloon (2.2) which is inflated,
- at least one carrier trocar (3) which has a hollow, preferably cylindrical body, wherein the end of the body close to the (A) aorta is sharp so that it can easily be guided to the aorta (A) puncture, which has a lumen in a diameter suitable for carrying deflated balloon (2.2) catheter (2) therein, and which enables to place the catheter (2) inside the aorta (A) after aorta (A) puncture,
- at least one punch (4) which is comprised of at least two separate pieces, and which enables to perform aortotomy by connecting these pieces and attaching to the body of the catheter (2),
  - at least one socket clips (4.1) which is provided on inner wall of one of the pieces forming the punch (4),
  - at least one tooth clips (4.2) which is provided on inner wall of one of the pieces forming the punch (4), and which engages to a socket clips (4.1) on the inner wall of another piece,
  - at least one blade (4.3) which is provided on the surface of at least one of the symmetrical pieces forming the punch (4) directing towards the aorta (A), and which determines the diameter of the aortotomy to be opened.
The inventive manual proximal anastomose device (1) is comprised of three main pieces, namely carrier trocar (3), a catheter (2) which has balloon (2.2) thereon, and a round punch (4) for aortotomy.

The carrier trocar (3) which is used in a preferred embodiment of the invention is manufactured from a nonflexible material such as metal, hard, plastic etc., it has a hollow, preferably cylindrical body (Figure 1). The carrier trocar (3) is in diameter of nearly 7mm, in length of 100mm, and has a lumen (inner opening) in diameter of 5mm. The length of the carrier trocar (3) and its inner radius are not fixed, it can be manufactured in desired sizes. The related carrier trocar (3) bears a balloon (2.2) catheter (2) which is not inflated in the lumen therein, and it enables the balloon (2.2) catheter (2) to be placed inside the aorta (A) after aorta (A) puncture. After the balloon (2.2) catheter (2) is placed inside the aorta (A) and the related balloon (2.2) is inflated, the carrier trocar (3) is removed and left outside the area.

The catheter (2) used in a preferred embodiment of the invention is manufactured from a bendable, flexible material, and it has a hollow cylindrical structure in diameter of approximately 3mm and in length of 100mm (Figure 2). There is a lumen inside it which allows liquid passing in order to inflate balloon (2.2) in diameter of 1.5mm. There is a mouth (2.4) with stopper (for example with a mechanism that will prevent the liquid to leak back as in liquid valves), that is compatible with the plastic injector tips in use, for inflating the balloon (2.2) with liquid at the proximal end (2.3) (the end close to the surgeon). Its distal end (2.1) (the end inside the aorta (A)) is continuation of the balloon (2.2) the features and the shape of which will be described below and the special structure (the balloon (2.2)) enabling the coaptation of it to the aorta (A) wall (completely coinciding the aorta (A) wall surface and the balloon (2.2) surface on each other such that there will be no leak). The distal end (2.1) of the related lumen with diameter of 1.5mm opens inside the balloon (2.2) to be inflated; therefore the liquid given from the proximal end (2.3) inflates the balloon (2.2) and enables the balloon (2.2) to take the desired form for coaptation. After anastomose, the balloon (2.2) is deflated by
aspiring (retracting) the liquid which is given via the related lumen, and it is taken outside from the aortotomy by means of its flexible structure.

The balloon (2.2) is released (Figure 4) by pushing the catheter (2) about 10mm towards the aorta (A) lumen from the carrier trocar (3) (Figure 3) placed after aorta (A) puncture, and the carrier trocar (3) is pulled from the proximal end (2.3) of the catheter and removed from the area (Figure 5). After the balloon (2.2) is inflated with a liquid (for example serum physiologic) given through the mouth (2.4) of the catheter with stopper present at the proximal end (2.3) (Figure 6), its coaptation is provided with the traction applied towards the aorta (A) wall from the proximal end (2.3) of the catheter (2) (Figure 7).

Various areas of the balloon (2.2) are manufactured from silicone or similar material suitable for exhibiting different rates of rigidity and flexibility. As a general description, with the traction done for coaptation (full contact to inner surface of the aorta (A) from every point) after the balloon (2.2) is inflated, balloon (2.2) surfaces contacting the aorta (A) wall will flex sideways with 90 degree angle to the traction vector to cover the possible openings between the aorta (A) wall and balloon (2.2) such that they will not let any leakage. On the contrary, balloon (2.2) base facing the aorta (A) lumen is manufactured in a form that flexes less and has a harder structure. Therefore, the force distribution due to traction is transferred to only the soft surface contacting the aorta (A) wall, and the coaptation can be provided perfectly (Figure 7).

When the balloon (2.2) is inflated in the aorta (A), a hollow (H) allowing the suture passing from the area remaining between the surfaces contacting the aorta (A) wall is formed around the catheter (2). The approximate scale relation of the surface of the balloon (2.2) contacting the aorta (A) wall while it is inflated, the hollow (H) and the catheter (2) and the aortotomy is shown as a plan view in figure 8. The ring on the outside, among the five nested rings, shows the widest border of the balloon (2.2), one inner ring shows the hollow (H) border of the
balloon (2.2), one inner ring shows the diameter of the aortotomy, and one inner ring shows the diameter of the catheter (2). The innermost ring shows the lumen inside the catheter (2) (Figure 8).

In a preferred embodiment of the invention, one of the annular punches (4) produced in diameters of 7.1mm, 8.1 mm, 9.1 mm is used for aortotomy. However, these diameters can be changed and produced differently according to need. A punch (4) which is comprised of two semi-cylinders can be attached to the catheter (2) carrying the balloon (2.2) at the end having a body diameter of nearly 3mm via a lock mechanism (socket clips (4.1) and tooth clips (4.2)) present in the structure of the semi-cylinders, and can move back and forth on the catheter (2) and right-left around its own axis easily (Figures 9, 10, 11). There is an annular blade (4.3) for aortotomy on their surfaces facing the aorta (A), symmetrical with their structures and approximately the half of their lengths are embedded in their bodies, and the diameter of the related blade (4.3) determines the diameter of the aortotomy which will be opened. The blade (4.3) diameters are determined as approximately 7.1 mm, 8.1mm, and 9.1 mm so that it will be compatible with various anastomose sizes. However, these diameters can be changed and produced differently according to need. After the balloon (2.2) is inflated and the traction is applied, the semi-cylinders of the punch (4) in a suitable diameter are attached to the catheter (2) and lowered until the aorta (A) wall in a direction that the blades (4.3) will face the aorta (A) wall (Figures 12-13). The aorta (A) wall in a size as large as the diameter of the blade (4.3) is excised and the aortotomy is performed by rotating the punch (4) to right-left around its own axis by being pushed slightly, in other words sliding annularly. With this method, an aortotomy centering the balloon (2.2) hollow (H), therefore providing an equal distance for needle (N) passing for each wall is performed; the annular piece excised from the aorta (A) is taken to the upper part of the catheter (2) safely just like a button passed to a thread (Y) and it is removed from the surgical area (Figures 14-15). The edges of the aortotomy are more clear-cut
compared to the aortotomies that are expanded via the punches used routinely, increasing the safety of the anastomose.

After this step, the sutures between the graft vein (G) which will be anastomosed and the aortotomy are performed (Figure 16). During anastomose, the surface of the hollow (H) part of the balloon (2.2) designed to let the passing of the needle (N) easier is manufactured from a flexible material or in a structure such that it will preserve the hollow (H) shape without deforming during traction and it can move out of the aortotomy when the balloon (2.2) is deflated. The final state of this shape can be changed depending on the raw material to be used in accordance with the purpose. In order to gain space while suturing, the catheter (2) in a flexible form and kept in traction can be flexed towards the part which is not sutured, and therefore more space can be provided. This maneuver which is performed towards the opposite side can be repeated for each suture all around symmetrically. After the sutures are performed in a loose way around the whole line, the balloon (2.2) of the catheter is deflated and removed from the aortotomy; the loose anastomose sutures are tightened and the graft vein (G) is fitted into the aortotomy; the suture is knotted and the anastomose is completed (Figure 17).
CLAIMS

1. A proximal anastomosing device (1), which enables to perform proximal
anastomoses to be performed on the ascending aorta (A) by providing
bloodless area required without using side clamp in coronary by-pass surgery,
especially characterized by

- at least one catheter which has a hollow, preferably cylindrical body,
  - at least one balloon (2.2) which is located on the body of catheter (2) in
deflated form in a way that it will surround that part of the related body of
the catheter (2) as the distal end (2.1) of the catheter (2) close to the aorta
(A), and which enables to eliminate blood leak outwards from the aorta (A)
by enabling full contact on inner surface of the aorta (A) with its flexible
edges after the traction which will be applied towards the entrance hole of
the aorta (A) wall following the inflation inside the aorta (A),
  - at least one mouth (2.4) which is located at the proximal end (2.3) of the
catheter (2) far from the aorta (A), and which provides an opening for
inflating the deflated balloon (2.2) and deflating the related balloon (2.2)
which is inflated,
- at least one carrier trocar (3) which has a hollow, preferably cylindrical body,
  wherein the end of the body close to the (A) aorta is sharp so that it can easily
be guided to the aorta (A) puncture, which has a lumen in a diameter suitable
for carrying deflated balloon (2.2) catheter (2) therein, and which enables to
place the catheter (2) inside the aorta (A) after aorta (A) puncture,
- at least one punch (4) which is comprised of at least two separate pieces, and
  which enables to perform aortotomy by connecting these pieces and attaching
to the body of the catheter (2),
  - at least one blade (4.3) which is provided on the surface of at least one of
the pieces forming the punch (4) directing towards the aorta (A), and which
determines the diameter of the aortotomy to be opened.
2. A proximal anastomose device (1), according to claim 1, characterized by carrier trocar (3) which is manufactured from a nonflexible material.

3. A proximal anastomose device (1), according to claim 1, characterized by catheter (2) which is manufactured from a bendable, flexible material.

4. A proximal anastomose device (1) according to claim 1 or 3, characterized by catheter (2) which has a lumen allowing liquid passing in order to inflate the balloon (2.2).

5. A proximal anastomose device (1) according to claim 1, characterized by mouth (2.4) which is compatible with the plastic injector tips and prevents the liquid to return back in order to inflate the balloon (2.2) at the proximal end (2.3).

6. A proximal anastomose device (1) according to claim 1, characterized by balloon (2.2) which is manufactured from a silicone or similar material such that its surfaces contacting the aorta (A) wall and its base facing the aorta (A) lumen will show different rigidity and flexibility.

7. A proximal anastomose device (1) according to claim 6, characterized by balloon (2.2) the surfaces of which contacting the aorta (A) wall enable to close the openings between the aorta (A) wall and itself by flexing with a 90 degree angle to the traction vector with the traction to be applied after inflating for coaptation such that it will not let any leakage.

8. A proximal anastomose device (1) according to claim 6 or 7, characterized by balloon (2.2) the base of which facing the aorta (A) lumen is manufactured in a harder structure flexing less relative to the surfaces contacting the aorta
(A) wall so that the force distribution caused by traction is transferred only to the soft surface contacting the aorta (A) wall.

9. A proximal anastomose device (1) according to claim 1 or 7, characterized by balloon (2.2) which forms a hollow (H) allowing suture passing through the area between the surfaces contacting the aorta (A) wall around the catheter (2) when it is inflated while it is inside the aorta (A).

10. A proximal anastomose device (1) according to claim 1, characterized by punch (4) which is comprised of at least two separate pieces and attached to the catheter (2) body by connecting these pieces.

11. A proximal anastomose device (1) according to claim 1, characterized by at least one lock mechanism which enables connection of the punch (4) comprised of two separate symmetrical semi-cylinders.

12. A proximal anastomose device (1) according to claim 11, characterized by at least one socket clips (4.1) which is located on the inner wall of one of the pieces forming the punch (4).

13. A proximal anastomose device (1) according to claim 12, characterized by at least one tooth clips (4.2) which is provided on inner wall of one of the pieces forming the punch (4), and which engages to a socket clips (4.1) on the inner wall of other piece.

14. A proximal anastomose device (1) according to claim 1 or 11, characterized by punch (4) which can move back and forth on the catheter (2) and right-left around its own axis by means of the lumen therein.
15. A proximal anastomose device (1) according to claim 11, characterized by blade (4.3) in form of a semi-circle which is embedded on at least one of the pieces forming the punch.
### A. CLASSIFICATION OF SUBJECT MATTER

| A61B17/11 | A61B17/3205 | A61B17/00 |

According to International Patent Classification (IPC) or to both national classification and IPC

### B. FIELDS SEARCHED

- Minimum documentation searched (classification system followed by classification symbols)
  - A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

- EPO-Internal, WPI Data

### C. DOCUMENTS CONSIDERED TO BE RELEVANT

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### Date of the actual completion of the international search

30 August 2016

### Date of mailing of the international search report

06/09/2016

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- NL-2280 HV Rijswijk
- Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016

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