Expandable prosthesis for sutureless anastomosis in thoracic aorta prosthetic substitution

Abstract  Objective. Most complications of descending aorta prosthetic substitution seem mainly to be related directly (ischemia to distal organs, i.e. liver, kidney, spinal cord) or indirectly (extracorporeal circulation or shunts and systemic heparinization complications) to the duration of blood flow interruption. The purpose of this study is to report the results of animal experimentation of a new device for sutureless prosthetic substitution of the descending thoracic aorta, with a very short cross-clamping phase.

Methods. The device consists of expandable loops of stainless steel wires, sewn to the proximal end of a Dacron prosthesis. The stainless steel wire loops can be expanded and tightened by activating a removable guide in such a way that the prosthesis varies its diameter, while maintaining a regular cylindrical shape. The device was prepared in two different configurations, one for long segments (expandable prosthesis end) and the other to be used for very short segments or as an anastomotic ring between prosthetic or vascular stumps (quick anastomotic ring). The expandable prosthesis end was tested in swine experiments by performing the prosthetic substitution of the first 10 cm of descending cross-clamped aorta, the prosthesis being fixed with the device both at the proximal and the distal ends (six experiments). All animals survived the procedure, that was accomplished with a very short cross-clamping time. The quick anastomotic ring was used to anastomose two prosthesis ends, at the middle of the prosthetic segment used for descending aorta substitution (two swine), to perform the distal anastomosis in the same model of descending aorta substitution (one swine) and simply to re-anastomose a subtotally transected descending aorta (one swine).

Results. The present experience proved the reliability of the device to carry out a sutureless, accurate, simple and quick anastomosis. Its advantage over an intraluminal ringed prosthesis is much easier insertion of the retracted wired end into the vascular stumps, thus allowing for a prosthetic diameter appropriate to the substituted vessel.

Conclusions. The reduced cross-clamping feature of the device would suggest its use mainly in thoracic aorta prosthetic substitution for the prevention of ischemic damage to distal organs; it can also be used to advantage wherever an end-to-end vascular or prosthetic anastomosis is indicated, providing an accurate, stented anastomosis. [Eur J Cardio-thorac Surg (1996) 10: 1003–1009]

Key words  Descending aorta · Aortic aneurysm · Spinal cord ischemia · Paraplegia
Introduction

Most complications of aorta prosthetic substitution seem mainly to be related directly (ischemia to distal organs, i.e. liver, kidney, spinal cord) or indirectly (extracorporeal circulation (ECC)) or shunts and systemic heparinization complications) to blood flow interruption.

Spinal cord ischemic injury is the most dreaded complication of prosthetic substitution of the descending aorta. Although many techniques (shunts, ECC techniques, spinal fluid decompression, deep hypothermia etc. [5, 8, 11, 17]) have been tested, not one of them is still accepted in clinical practice as being able to completely prevent this complication, whose incidence remains significant [6, 7]. There is, however, general agreement that the incidence of spinal cord injury is directly proportional to the duration of the aortic cross-clamping phase. Accordingly, it can be reasonably hypothesized that if the cross-clamping time is maintained under the limit of the ischemic tolerance of nervous tissue (3–5 min in normothermia, 30–40 min in deep hypothermia), damage can be virtually prevented, at least if critical tributaries to the spinal cord are not included in the substituted segment.

The purpose of this paper is to report the animal experimentation of a new device for sutureless vascular anastomosis particularly useful in aorta prosthetic substitution, which substantially reduces the cross-clamping time.

Material and methods

Device

The device consists of expandable loops of stainless steel wire, sewn to a vascular prosthesis (Albograft, Sorin Biomedica Cardio, Spa, Strada per Crescentino, 13040, Saluggia, Vercelli (It)) arranged in several circular loops. Traction on the wires by an activating guide allows the loops to be expanded and tightened in such a way that the prosthesis varies its diameter, while maintaining a regular cylindrical shape. The prosthesis end then becomes a rigid cylindrical ring with variable and controllable diameter. Although the expandable segment lumen remains regularly cylindrical from its maximal to minimal aperture, the increasing thickness of its wall due to the fabric folding, significantly narrows the opening range in terms of clinical use. The wall thickness/diameter ratio seems to be acceptable for clinical use when the final aperture is not less than 70% of the maximal diameter, an aperture slightly smaller than that represented in the second square from left

Fig. 1 Working principle. The working principle of the device relies on a number of metallic wires, sewn to a vascular prosthesis (Albograft, Sorin Biomedica Cardio, Spa, Strada per Crescentino, 13040, Saluggia, Vercelli (It)) arranged in several circular loops. Traction on the wires by an activating guide allows the loops to be expanded and tightened in such a way that the prosthesis varies its diameter, while maintaining a regular cylindrical shape. The prosthesis end then becomes a rigid cylindrical ring, approximately 1/2 the maximal diameter, with a variable and controllable diameter (Fig. 1). The device was prepared in two versions, one for long vascular segments (expandable prosthesis end) (Fig. 2) and the other to be used for prosthetic substitution of very short vascular segments (length <2 x vessel diameter) or as a device for quick end-to-end anastomosis between prosthetic or vascular stumps (quick anastomotic ring) (Fig. 3).

In the version for long segments, the expandable stainless steel wire loops were prepared on a separate prosthesis segment to be associated with each prosthesis end at the time of use; the prosthesis segment required for substitution is cut to the appropriate length and sutured to this expandable segment before cross-clamping (Fig. 2b). In this way it is possible to prepare expandable segments of differ-
Fig. 2 Expandable prosthesis end. The device is realized in different sizes and is fitted with a flexible guide with its activating handle. The appropriate opening can be temporarily fixed by turning a knob sited at the guide handle (arrow) (a). The prosthesis segment required for substitution is cut at the appropriate length and sutured inside the expandable segment (b) before cross-clamping. The metallic wires of the expandable prosthesis end provide a rigid ring, approximately 1/2 its maximum diameter in length. When the blood flow is reestablished, the guide is cut as close as possible to the expandable end after having squeezed and kinked the sliding metallic rings, fitted along each of its branches (arrow) (c). The device allows the prosthesis end diameter to be reduced by up to 20–40% of its maximal diameter (d). The optimal opening of the device when in site is probably 90% of its maximal aperture; this offers a good wall thickness lumen diameter ratio, while still keeping an extra-aperture reserve in case of size mismatch (see note at the end of the paper).

Fig. 3 Quick anastomotic ring. The device (upper circle a: the ring in the tightened position; lower circle b: the ring in the expanded position) is based on the same working principle, the activating guide entering the prosthetic segment at the middle and controlling the expansion of both ends simultaneously. This facilitates the use in very short prosthetic substitution, the optimal length-diameter ratio being ≥1:≤2. The device can also be used for quick anastomosis between vascular and/or prosthetic stumps. Up, left: just one stitch provides approximation of the stumps at the posterior wall. Middle, left: the device is inserted in the closed position. Middle, right: while the stumps’ anterior walls are approximated by forceps or, preferably, by an extra stitch, the device is opened until a firm contact with the stump wall is achieved. Bottom, right: an umbilical tape secures hemostasis and prosthetic stabilization.
The use of the expandable segment at both ends of the prosthesis is practical when the segment to be substituted is 10 cm or longer (Fig. 4, I, a); for shorter segments the activating guide at each end may hamper the prosthesis manipulation and the procedure may be cumbersome as a result. In these cases it is more practical to position each expandable segment with part of the prosthesis separately (Fig. 4, II, a). The prosthesis stumps can be anastomosed together thereafter, using the quick anastomotic ring (Fig. 4, II, b-e). This quick anastomotic ring is based on the same working principle, with different positioning of the activating guide and the wire loops (Fig. 3). The activating guide is placed at the middle of the ring and controls the expansion of the two ends simultaneously. During the insertion phase the segment can be reduced by up to 40% its maximal expanded diameter. Optimal ratios between the length and the expanded diameter for the device in this situation are between 1 and 2.

Experimental models

**Expandable prosthesis end**

The device was positioned in the first segment (10 cm) of the descending thoracic aorta in six swine (20-45 kg) experiments (Exp. Mod. 1); both the distal and the proximal ends of the prosthesis were fitted with the expandable segments, thus both anastomoses were carried out with the device. After cross-clamping, a wide longitudinal aortotomy was prepared; the distal and proximal ends of the prosthesis were positioned and stabilized there by over-extension of the expandable segment against the inner aortic wall, by activating the guide. An umbilical tape was tied externally around each expandable prosthesis end. The clamps were removed and, after the blood flow had been re-established, the activating guide was disconnected. No bypass or any other spinal cord protection measure was used. A single dose of heparin 100 UI/kg IV was given just before cross-clamping; no other medications were given thereafter or in the postoperative period. The animals were killed 2 weeks later.

**Quick anastomotic ring**

The device was used to anastomose two prosthesis ends (Fig. 3), at the middle of the prosthetic segment used for descending aorta substitution (two swine) (Exp. Mod. 2, Fig. 4 II), to perform the distal anastomosis of the prosthetic segment to the aortic stump at each end.
anastomosis between the prosthesis end and the distal aortic stump in the same model of descending aorta substitution (one swine) \(\text{Exp. Mod. 3}\) and simply to re-anastomose a subtotally transected descending aorta (one swine) \(\text{Exp. Mod. 4}\), a model very similar to the isthmic traumatic rupture repair.

### Results

The procedure was very simple to carry out and the prosthesis was positioned very quickly both in the expandable aorta end and in the quick anastomotic ring experimental models. After a learning curve both for the technique and for prototype realization, the prosthetic substitution was achieved with decreasing cross-clamping time, the shortest being 6 min for descending aorta substitution \(\text{Exp. Mod. 1}\). Hemostasis was not constantly and reliably achieved without external ligature; thus we always completed the procedure with the expandable aorta end stabilization using an umbilical tape ligature. All animals survived the procedure without detectable neurologic deficits and the prosthesis was found to be normally patent at sacrifice. The maximal outer diameter of the devices used in these experiments measured 16–18 mm, the inner diameter being 10–14 mm. These devices are quite over-dimensioned in comparison with the sizes of the aortae of these swine and to some extent hampered the procedure.

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**Fig. 5** Relationships between the aortic diameter and the intraluminal prostheses derive from the fact that their introduction into the vascular stump is not easy. In fact, when the aorta is clamped its diameter narrows considerably\(^1\) [16]; that and the thickness of the aortic wall itself, which is approximately 8–20% of its outer diameter, reduce the suitable diameter of the ringed prosthesis that can be placed into the stump. Moreover, since the aortic wall has a floppy consistency, a significant gap must be left between the inner clamped aortic wall and the outer ring prosthesis diameters; otherwise friction would prevent a quick positioning. In practice, to position an intraluminal ringed prosthesis more quickly than to perform a manual suture, a prosthesis diameter substantially smaller than that which would be appropriate must often be used. It is easy to see how the expandable prosthesis overcomes all these disadvantages, that presumably prevented the large clinical application of Lemole’s device.

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\(^1\) Previous experience in the descending aorta of normal swine \(\text{Large White, 20-45 kg}\) showed that when the intravascular pressure passes from 120 to 40 mmHg the measured external diameter reduction was within 6.5–13.4% [14].

### Discussion

The general biologically benign nature of aortic diseases implies a substantially normal life-expectancy when prosthetic substitution is successfully achieved; this makes the devastating, if not fatal, neurologic complications of these operations particularly striking and dreadful, especially as they are still largely unpredictable and unavoidable in spite of the sophisticated maneuvers attempted for their prevention \([5-8, 11, 17]\).

Ideally, if the cross-clamping time could be kept within the ischemic tolerance of the nervous tissue \(3–5\) min in normothermia, \(30–40\) min in deep hypothermia \([10]\), it seems reasonable to expect a virtually complete prevention of neurologic complications, at least if critical tributaries to the nervous tissues are not included in the substituted segment, or are revascularized within this time lapse. Since almost the whole cross-clamping time is spent on accomplishing the anastomoses, it seems reasonable to focus research on devices for accelerating this procedure. One of the working principles of the device developed \([9]\) is the connection of the vascular stump to the prosthesis by means of a sutureless procedure, i.e., by external ligature of the vascular stumps against a rigid annular structure in contact with the prosthesis ends. This principle, the idea of which is very attractive, is not new, dating as far back as the beginning of the century; in 1990, in fact, Payr reported to the German Surgical Society \([16]\) results on animal experiments of his device for sutureless anastomosis, which is essentially based on this principle. It is curious to note that this manner of performing vascular anastomosis even precedes the Carrel’s Nobel price (1912) granted reports \([3, 4]\) on the triangulation technique, that in fact represented the basis of the modern vascular surgery technique.

A few years ago intraluminal ringed prostheses were used quite extensively \([12]\) in aortic substitution by a number of surgeons \([1, 6]\). However in spite of the ideal attractiveness of the procedure, the intraluminal ringed prostheses failed to replace standard manual sutures and, even though commercially available, they are used only occasionally at this point in time. The reason for this probably lies in the fact that even though the anastomosis is very quick (just the time for a ligature tie), the positioning of a prosthesis of appropriate diameter into the vascular stump is not. This is due to three factors at least \(\text{Fig. 5}: 1)\) there is a substantial reduction of the vascular lumen when the aorta is clamped, an adverse condition already outlined in...
the Payr report [16], 2) the thickness of the aortic wall (approximately 8–20% of the diameter) further reduces the viable prosthesis diameter, 3) due to the floppy consistency of the aortic wall, a significant gap between the internal surface of the prosthesis and the external ring diameter must be left to allow the ring to be easily slipped into the aortic stumps. The possibility of adjusting the aperture opening means, theoretically, hemostasis can be obtained by over expanding the wired prosthesis end, pushed from inside against the aortic wall. The present experience was inconsistent in this regard, thus we think that an external ligature is advisable both to assure hemostasis and to prevent prosthesis dislocation.

To overcome these adverse factors the prosthesis was made expandable, an approach attempted by others in a different way [13], thus allowing an easier and quicker insertion into the aortic stumps. The possibility of adjusting the prosthesis opening means, theoretically, hemostasis can be obtained by over expanding the wired prosthesis end, pushed from inside against the aortic wall. The present experience was inconsistent in this regard, thus we think that an external ligature is advisable both to assure hemostasis and to prevent prosthesis dislocation.

After a learning curve, we are now able to realize devices in both versions in the entire size range between 42 mm and 12 mm (outer diameter) of maximal aperture, that can be retracted up to 20–40% during the insertion phase. Even though the expandable segment lumen remains regularly cylindrical within a quite wide diameter range, the increasing thickness of its wall as the diameter is reduced significantly narrows the aperture, and no one device should be considered as suitable for all aortic sizes; the wall thickness diameter ratio seems to be acceptable for clinical use when the final aperture is set at no less than 70% (Fig. 1). In practice, it is assumed that the optimal aperture of each single expandable prosthesis end, defined as 90% of its maximal opening, will fit the inner diameter of the perfused aorta; the latter can be quite accurately estimated on angiographic contrast CT scan.

The device in the two configurations realized was tested only in short-term survival experiments, and thus data on the long-term incidence of thrombosis or migration are not yet available. The possible realization of a composite graft with the expandable device fitted at each graft branch end leads to the interesting consideration of its use in aortic arch substitution where all the anastomoses (distal arch, left carotid and anonymous artery and proximal arch) can be quickly performed with this technique, greatly reducing the circulatory arrest time in this still dangerous area. Preliminary experiments in swine with this model have provided very promising results [15].

Note Since the manuscript submission further experience showed that when the expandable prosthesis is wetted or enters in contact with blood the wires loops become fixed and further variation of the aperture is no longer possible. This makes the wires fixation by squeezing the metallic rings not necessary to stabilize the aperture; on the other end great attention should be paid to avoid prosthesis wetting (avoid preclotting, bloodless and dry surgical field) during positioning until the final aperture is reached.

Acknowledgements We are grateful to the Officina Meccanica TRE RE, Castelletto di Branduzzo (PV), as well as to the many students of Dept. of Surgery (Tiziana Barbano, Federica Maestri, Federica Baldini, Alessandro Aluffi, Antonio Deroberto, Giovanna Barison) and to the Casa Del Giovanni San Giuseppe, Pavía, for their dedicated cooperation in prototype realization. The work was partially supported by IRCCS San Matteo, Pavía, Italy.

References


Forthcoming meetings and events

1996

December 4–7, 1996 – Rio Mar, Puerto Rico
8th Cardiac & General Thoracic Surgery: Update.
Information: American College of Chest Physicians, 3300 Dundee Road, Northbrook, IL 60062, USA
Tel. +1 847 98 14 00, Fax +1 847 98 54 60

December 14, 1996 – Berlin, Germany
Symposium on "Organ Preservation in Heart Transplantation – Theory, Clinical Use and Legal Issues", Deutsches Herz-Zentrum, Berlin
Information: Dr. M. Loche, Deutsches Herz-Zentrum, Berlin, Augustenburger Platz 1, D-13353 Berlin, Germany
Tel. +49 30 45 93 20 00, Fax +49 30 45 93 21 00

1997

January 27–29, 1997 – San Diego, USA
The 33rd Annual Meeting of The Society of Thoracic Surgeons
Information: 401 N. Michigan Ave., Chicago, IL 60611–4267, USA
Tel. +1 31 26 44 66 10, Fax +1 31 25 27 66 35

February 13–15, 1997 – San Diego, California, USA
Pathophysiology & techniques of Cardiopulmonary bypass: The 17th Annual San Diego Cardiothoracic Surgery Symposium, San Diego Marriott Hotel & Marina, San Diego, CA, USA
Information: C. R. E. F., P.O. Box 23220, San Diego, CA 92193, USA,
Fax 0 01 61 95 41 14 47, Email: 742241, 1523@compuserve.com

February 27–28, 1997 – Marseille, France
3rd Live Tele Conference on “Valvular Autografts and Homografts Banking and Surgery”, 140 chemin de l’Armée d’Afrique, Marseille, France
Information: M. P.C., “Le Sergeant Major”, 140 chemin de l’Armée d’Afrique, 13901 Marseille, France,
Tel. +33 04 91 42 18 18, Fax +33 04 91 42 54 37

March 16–20, 1997 – Anaheim, CA, USA
American College of Cardiology
Information: 13 Elm St., Manchester, MA 01944, USA
Tel. +1 50 85 26 83 30, Fax +1 50 85 26 75 21

April 11–12, 1997 – Noordwijk, The Netherlands
Stentless Bioprostheses Second International Symposium
Information: Congress Office Tonne Verdonk
St. Vicentiussstraat 11, NL-5664 GJ Geldrop, The Netherlands
Tel. +3 14 02 85 22 12, Fax +3 14 02 85 19 66

April 17–19, 1997 – Quebec, Canada
American Surgical Association
Information: 13 Elm St., Manchester, MA 01944, USA
Tel. +1 50 85 26 83 30, Fax +1 50 85 26 75 21

May 4–7, 1997 – Washington, DC, USA
The 77th Annual Meeting of The American Association for Thoracic Surgery
Information: 13 Elm St., Manchester, MA 01944, USA
Tel. +1 50 85 26 83 30, Fax +1 50 85 26 75 21

May 11–15, 1997 – Honolulu, Hawaii
The Second World Congress of Pediatric Cardiology and Cardiac Surgery, Hilton Hawaiian Village, Honolulu, Hawaii
Information: c/o International Communications Specialists Inc., Kasho Building, 2F, 2-14-9, Nihombashi, Chuo-ku, Tokyo 103, Japan. Fax. +8 13 32 73 24 45