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Work in progress report - Experimental

Expandable device type III for easy and reliable approximation of dissection layers in sutureless aortic anastomosis. Ex vivo experimental study

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Abstract

In past years, we developed expandable devices (type I and II) for sutureless aortic anastomosis. We have now further modified the device (type III) incorporating a second expandable ring, external to the main one, which can be operated contrariwise in such a way that the aortic wall (i.e. the dissection layers) is compressed between the two expandable rings, providing full control on both the layers compression pressure and the anastomosis final diameter. The device was evaluated in ex vivo experimental models of swine aortic arch fresh samples; air-tight sealing at increasing endovascular pressures was also evaluated and compared with sealing achieved by standard suturing. Ex vivo data suggest that the present version of the device can be used easily and quickly also in elliptical, asymmetric ‘oblique’ anastomosis as when concavity arch is involved. Perfect air-tight sealing of the anastomosis was verified at endovascular pressures up to 150 mmHg, while standard suture cannot withstand even minimal endovascular air pressure. Compared to the previous versions, the present device is less bulky and softer, can be used also for concavity arch resection and provides full and standardizable control on dissection layers stable and sealed approximation.

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Keywords: Sutureless anastomosis; Aorta acute dissection; Expandable prosthesis

1. Introduction

A number of years ago, we developed an expandable device for aortic sutureless anastomosis in two versions (type I and II), which underwent many modifications and refinements1, as well as extensive testing in ex vivo and in vivo animal experiments [1, 2]. A few clinical cases were also successfully treated with this device [3, 4].

The purpose of this report is to describe a version of the device (type III), in which the external ligature is substituted by an expandable sleeve, which is based essentially on the same working principle as the inner sleeve, but activated contrariwise (Fig. 1, upper left squares). Thus, the vascular stump is compressed between two sleeves (Fig. 1, upper square), with variable and controllable diameters, which provide full control of the pressure (amount and surface of its application) applied to the vascular stump (Video 1). The primary aim of this new version of the device is to extend its use to acute ascending aorta and arch dissection in order to simplify the technique, to reduce the ischemic time, to improve hemostasis of the anastomosis line and to achieve reliable, stable and sealed approximation of the dissection layers in this complex surgical setting.

2. Materials and methods

The device was tested in ex vivo experimental models using fresh swine aorta samples in two different settings, i.e. orthogonal application on ascending aorta (model 1: aortic anastomosis outer diameter 24±3 mm, wall thickness 2±0.3 mm; 5 experiments) and elliptical, asymmetric ‘oblique’ application on distal ascending aorta extended to the hemi-arch concavity (model 2: aortic ellipse outer diameters minimum 24±3 mm, maximum 30±3 mm, angle between arch concavity and ascending aorta ~30°; 5 experiments).

In addition to assessing the time required for positioning the device and its handiness, we also evaluated the quality of the device-aortic stump seal achieved in these two sites of application using the model illustrated in Fig. 2, which allows the air-tightness of the anastomosis to be tested at increasing endovascular pressures. For this purpose, the outer surface of the inner sleeve was wrapped by a latex cuff (Fig. 2, top squares) in order to overcome the problem of the porosity of the dacron graft and the requirement for the connection of the tubular graft to the proximal end of the inner sleeve as in its final clinical use.

Conflict of interest disclosure: The author is entitled to patents concerning the devices reported in this paper.

1 See video at url: http://www.fondazionecarrel.org/ejets/nd.html.
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Fig. 1. Upper square: The most recent versions of the type I and II devices (see video at url: http://www.fondazionecarrel.org/ejcts/nd.html) can be now activated by a single guide, further simplifying their use. The side sketches outline the different shape and orientation of the nitinol wire-frame. The type III device incorporates an external sleeve that substitutes the external ligature, thus allowing standardization of the pressure applied to the vascular stump wall. The wire-frame of the device is quite soft and compliant, and can be easily compressed and widely deformed while maintaining perfect reciprocal alignment of the internal and external sleeves (top right squares) (Video 1). Lower square: Acting only on the activating guide of the inner sleeve, the retracted inner sleeve becomes fully visible (a) and can be inserted into the vascular stump (a’) and then expanded as much as the vascular wall can be distended (b) by acting contrariwise on the same guide. At this point, the outer sleeve is only slightly retracted towards the aortic wall (c) using its own guide. The device complies easily with different orientations of the aortic wall (c, white and red bars), allowing elliptical, asymmetric ‘oblique’ anastomosis. When the device has been positioned satisfactorily, the nitinol wires are permanently blocked by crushing the predisposed little titanium sleeve (c, blue arrows) and the guide is cut away. (Video 1).

The air-tightness of this device was also compared with that achieved by standard suturing (4–0 prolene running suture) of an approximately 3 cm incision of the aortic wall, just proximal to the site of application of the device.

3. Results

The ex vivo models allowed us to verify both the very easy and quick positioning of the device, which, requiring simply insertion and expansion, can be accomplished in a matter of seconds. A few adjustments with forceps of some parts of the aortic wall stump may be required, but these are quickly carried out. In all experiments the device was positioned in <2 min.

The device fully and easily complied with aortic anatomy, perfectly adapting to the elliptic, asymmetric ‘oblique’ stump resulting from inclusion of the arch concavity in the anastomosis.

Full and persistent air-tight sealing of the device/aortic wall coupling was verified at endovascular pressures of up to 150 mmHg in all experiments, including those involving an elliptic, ‘oblique’ anastomosis (Fig. 3a, b). As expected, standard vascular sutures were not air-tight even at pressures below 10 mmHg (Fig. 3c) (Video 2).

Fig. 2. Experimental model for underwater testing air-tight sealing at increasing intravascular pressures. The inner sleeve was wrapped by a latex cuff to overcome the problem of the porosity of the dacron graft and the requirement for the connection of the tubular graft to the proximal end of the inner sleeve (upper squares) (Video 2).

Fig. 3. (a) The air-tightness of the connection was verified at endovascular pressures of up to 150 mmHg in the normal cylindrical anastomosis of ascending aorta (white bars). (b) The same was verified when the anastomosis is irregularly oriented, such as when involves the arch concavity (Video 2). (c) As easily predictable, a standard suture (4–0 prolene) of an approximately 3 cm incision of the aortic wall cannot be proved airtight even at minor endovascular pressure (Video 2).
4. Discussion

The ex vivo experiments demonstrated that the device complies optimally with aortic anatomy, allowing an air-tight anastomosis even when its shape was not a regular cylinder, as occurs when the arch concavity is included. The substitution of the external ligature with an outer sleeve allowed also a significant reduction in the length of the inner sleeve, the final situation being then roughly comparable to that of double dacron strips buttressed at the anastomosis site for site approximation of the layers in these cases (Fig. 1, lower squares).

The working principle of the type III device enables the amount of pressure and the surface of its application on the vascular wall stump to be accurately dosed and standardized, which may be important when the aortic wall is critically weakened, as in acute dissection.

Obviously, the type III device can also be used for anastomosis at any other aortic segment, although it does, however, involve complete transection of the aorta at the anastomosis site and stump isolation for 1–1.5 cm all around, while the type I and II devices can be simply slipped into the longitudinally opened vessel, whose circumferential preparation is limited to encirclement with the external ligature. Indeed, with type I and II devices external encircling can even be avoided and effectively substituted by an endovascular purse-string suture (Fig. 4), obviously at the price of a slight prolongation of the ischemic time.

The working principle of the expandable device, i.e. fixation of the vascular stumps by external ligature against a rigid annular structure, is not new, being at the basis of the apparently first published idea of a vascular anastomosis device (intima to intima facing, absorbable magnesium ring) (Payr, 1900) [5]. However, in those years, Alexis Carrel was focusing his attention on suture techniques, already in use in the gastrointestinal tract, and was able to realize blood-tight, low thrombogenic, vascular anastomoses by careful refinements of the needles, threads and techniques for their use [6, 7], thus establishing the standard technique of vascular surgery. Technological evolution of substantially the same coupling principle (full thickness wall stump stitching) gave origin, around the middle of the past century, to stapling devices for automatization of anastomoses. However, while stapling devices have long since allowed standardization and simplification of digestive tract circular anastomosis, despite extensive research [8, 9], including our own [10], the stapling principle has so far failed to be of significant use for vascular anastomosis, which remains substantially the only basic surgical task still to be automatized.

In the 1970–1980s, a simplified Payr’s concept was revived with the introduction of intraluminal ringed prostheses, whose use in aortic substitution was quite extensively reported [10–13], although they eventually totally disappeared. The reasons for their clinical failure and the differences from the expandable device have been analyzed in detail elsewhere [1, 2]. One of the most important differences, however, is that the expandable sleeve is very thin, being formed substantially by a double layer of standard vascular dacron fabric, and can, therefore, be wholly and quickly colonized by fibroblasts and integrated with the aortic wall; the nitinol/polypropylene wire-frame forms a very thin and wide mesh net that accounts in fact for a very small proportion of the device’s volume and that offers no significant barrier to fibroblastic invasion of the dacron fabric and thus to stable biological integration of the device. In this regard expandable devices can, essentially, be considered mechanically and biologically substantially equivalent to the various aortic endovascular prosthetic devices currently in use, being of similar (or even lesser) consistency1. The now quite significant medium–to long-term clinical experience with endovascular devices has shown that late defective integration with fistulization is rare, albeit not unknown [14, 15]. In any case, expandable devices are much more limited in extension, occupying only a few millimeters at the site of the anastomosis and, more importantly, unlike with endovascular devices, a layer of dacron fabric prevents the nitinol wire-frame from coming into direct contact with the intimal aortic wall.

Expandable devices make performing an anastomosis a very simple task, which can be carried out in a few minutes, if not seconds. This then allows appreciation of the second main aim of the different principle of anastomosis (vascular stump compression between two rigid structures, i.e. an inner rigid ring and external ligature/outter rigid ring), which is to achieve easy and reliable hemostasis at the

1In contrast with endovascular device, however, expandable prosthesis can support external ligature tied-up to achieve hemostasis without significant reduction of the lumen, due to circular orientation of the nitinol loops.
anastomosis line. The 1970–1980s intraluminal ringed prosthesis in fact could not prove their clinical reliability in providing better blood-tight anastomoses than the suturing technique because they failed at an earlier phase, i.e. because the vascular stump-rigid tube coupling was neither easy nor stable.

The ability to achieve even air-tight anastomoses indicates the ‘mechanical’ superiority of this technique over the standard suture in this regard (Fig. 3c); indeed, this principle is currently exploited in many other fields of technology when connectors of stumps of fluid-conducting floppy tubes are required.

Of course, clinical experience over more than a century has shown that the standard suturing technique does not need to provide an air-tight anastomosis to ensure perfect hemostasis in virtually all clinical circumstances. In particular cases however (acute dissection, cystic medial necrosis, etc.), structural impairments of the aortic wall may necessitate additional maneuvers including buttressing graft strips, gluing and a variety of accessory techniques, whose efficacy at achieving hemostasis are not always fully predictable and that obviously further significantly prolong the period of ischemia in this most critical area. The coupling provided by compression of the stumps’ vascular wall between two rigid structures (i.e. inner and outer expandable rigid sleeves) may be then particularly useful in these cases, not only because of its ease and quickness, but also because it offers the best mechanical chance of blood-tightness; the expected advantages with regards to approximation of the dissecting layers and false lumen sealing relies on the same concept.

In conclusion, the device type III offers, for the first time, the unique features of easily and quickly allowing air-tight aortic anastomosis, which is obviously more efficient than standard suture in providing hemostasis as well as stable and sealed dissected layers approximation, and of perfectly complying with the irregularly elliptical and ‘oblique’ shape of the aortic anastomosis involving the distal ascending aorta and the arch concavity. Obviously controlled clinical studies are required to conclusively prove the long-term efficacy and safety of the type III device, as well as the type I and II devices; however, extensive experience in animal models, the results of a few clinical cases and, more important, the now quite wide and favorable clinical experience with the many, biologically equivalent, endo-vascular devices allows to hypothesize an equally favorable clinical outcome with no device-related adverse effects nor significant complications.

References


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