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# A new concentric double prosthesis for sutureless, magnetic-assisted aortic arch inclusion

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ABSTRACT

Acute dissection of the ascending aorta is a life-threatening condition in which the aortic wall develops one or more tears of the intima associated with intramural rupture of the media layer with subsequent formation of a two lumina vessel. The remaining outer layer is just the adventitia, with high risk of complete rupture. Vital organs may be under-perfused. Mortality rate in this acute event is about 50% if an emergent surgical procedure is not performed as soon as possible to replace the tract affected by the primary rupture. Nevertheless, the emergent surgical procedure is affected by high risk of mortality or severe neurologic sequelae, due to the need for deep hypothermia and cardiocirculatory arrest and different methods of cerebral protection. If the patient survives the acute event, a frequent outcome is the establishment of a chronic aortic dissection in the remaining aorta and late chronic dissecting aneurysm, usually starting from the surgical suture itself. Traumatism of surgical stitches and of direct blood flow pressure on weak aortic wall can be important contributing factors of the chronic disease. In conclusions, the majority of these patients undergoes a high risk operation without a complete solution of the disease.

We hypothesize that excluding the aortic layers from the blood direct flow and using an anastomotic technique which does not include surgical stitches could help to significantly reduce the recurrence of aortic dissection after the acute event and shorten hypothermic arrest duration. We devised a double tubular prosthesis consisting of two concentric artificial tubes between which the aortic wall is confined and excluded from direct blood flow. We also devised a magnetic assisted sutureless anastomotic technique that seals the aortic tissue between the two prostheses and avoids the perforation of the fragile aortic wall with surgical stitches. We are presenting here this new prototype and draw a few different models. Both acute and chronic diseases of the aorta could benefit from the proposed technique, although acute dissection is the ideal scenario for its use.



## Introduction

Acute aortic dissection is a life-threatening condition. It occurs when blood enters the medial layer of the aortic wall through a tear or penetrating ulcer in the intima and tracks along the media, forming a second blood-filled channel within the wall. Stanford classification identifies two main types, A and B, according to the position of the entry tear. Type A starts in the ascending aorta and the arch (60% of the cases) and has mandatory surgical indication while type B starts in the descending aorta, beyond the brachiocephalic vessels (40% of the cases) with indication to medical management by means of blood pressure control. Of all patients with type A dissection, 40% die within minutes and do not reach hospital in time. Of the remainder, 1% die every hour, therefore prompt diagnosis and treatment is a priority. Hospital mortality varies from 5% to 20% while incidence of neurological complications from 8% to 10% [1]. Aortic replacement is performed during moderate or deep hypothermia and cardiocirculatory arrest, with antegrade or retrograde cerebral perfusion. Surviving patients could have complicated outcome and the main lesion could not be completely solved by the emergent surgical procedure. The remaining aorta could maintain dissection or could have a recurrence of it early after surgical correction. A number of attempts to optimize the sealing of the dissected walls have not succeeded in lowering the incidence of chronic dissection. The chronic state is often complicated by progressive aneurysmal degeneration, chronic visceral or limb malperfusion, and persisting or recurrent pain or even rupture. A reoperation to treat the chronic disease often requires a second circulatory arrest with still high risk of cerebral damage and neurological complications. In conclusions, the majority of these patients undergoes a high risk operation without a complete solution of the disease.

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We hypothesize that a particular model of prosthesis and the use of magnetic forces in sealing zones could help to radically solve the acute state and reduce the incidence of chronic aneurysm. Such a prosthesis is targeted to surgically-treated, type A dissection but could also be employed in chronic aortic disease. We describe the current state of the art in this topic and illustrate a prototype model of the proposed device.

*Current surgical treatment techniques: open repair*

Emergent operation consists in the replacement of the aortic tract affected by the primary rupture of the intima (intimal tear). All the ascending aorta is usually replaced by tubular prosthesis with proximal anastomosis at the level of sino-tubular junction and distal anastomosis at the beginning of the aortic arch. This replacement should be extended if surgeon finds several intimal tears but the extension of replacement influences the duration of cardiocirculatory arrest and the risk for neurological complications, so the surgical treatment should consider risks and benefits of a more extended aortic replacement. Different suturing techniques are usually utilized with the main goal to seal together the aortic layers by means of surgical glues and Teflon felt reinforced anastomosis. Nevertheless, chronic persistence or recurrence of false lumen still represents a clinical problem [2–4]. The reported incidence of reoperations on the distal aorta varies between 4% and 28% of hospital survivors. One of the reasons of the persistence of false lumen is that surgical suture itself makes several millimetric intimal tears in the aortic wall, each of which could be the starting point of a new dissection. Moreover, direct anastomosis between tubular prosthesis and the remaining aorta could maintain the flow stress acting on a fragile aortic layers. This stress is increased by the stiffness of the tubular prosthesis that replaces the ascending aorta and reduces the elastic absorption of systolic pulse.

Improved surgical techniques continued to be introduced throughout the late 20th century, until the introduction of the frozen elephant trunk procedure that is a reproducible technique, effective in reducing the rate of late distal complications and that obtained good mid-term results [5].

Open surgery guarantees the best visual control of anatomy and structures to achieve radical correction but that is counterbalanced by the morbidity related to the duration of hypothermic arrest.

*Current endovascular and hybrid treatment techniques*

Alternative procedures to surgery are effective in treating the aortic arch with similar morbidity and mortality compared to surgical repair, despite addressing a more complex patient population [6].

*Hybrid arch repair* combines open and endovascular procedures to successfully treat aortic arch disease. This procedure requires an open sternotomy for debranching the supra-aortic trunks on the ascending aorta followed by an endovascular procedure to repair the diseased arch and descending thoracic aorta. Single, double, or total great vessel transposition is performed, followed by thoracic endovascular aortic repair (TEVAR).

In *chimney graft technique*, standard branched or fenestrated endovascular grafts are designed so that the blood is directed through the main body of the aortic stent graft and then through the branched or connection stents. The chimney graft technique was developed for patients with emergent aortic complications.

Different model of *custom-made scalloped or fenestrated and branched grafts* have been developed in last years, like arch branch graft by Cook Medical [7]. However, most of these devices have limited use and lack large cohort studies with long-term follow-up.

A particular *containment prosthesis* has recently been proposed for less invasive treatment of Marfan disease (PEARS, Personalised External Aortic Root Support) [8,9]. In this case an external prosthesis molded around a 3D model of patient's aorta is build and implanted around the native aorta without cardiopulmonary bypass.

Endovascular repair strategies offer advantages in comparison with open repair, as they are minimally invasive and do not require hypothermic circulatory arrest or rerouting of aortic blood flow, but sealing zone, device alignment and type 1 endoleaks remain major post-procedural problems that can limit or invalidate the late outcome [10–12].

*Uses of magnetic force in vascular surgery*

The idea of using magnetic attraction to act as a sutureless method for vascular anastomosis dates back to 1978 by Obora and Colleagues [13]. Obora published an original method of sutureless microvascular anastomosis based on magnet rings and hollow cogwheel-shaped metal devices held together by magnetic energy. This device allows the construction of end-to-end anastomosis and it reliability has been validated in an animal study in which it was possible to construct microanastomoses in about 8 min, reducing the technical demand of the procedure. Another use in coronary artery surgery is the Magnetic Vascular Port (MVP) system developed by Ventrica Inc, Fremont, CA, USA. The MVP system [14] consists of two sets of magnetic clips (three clips per set) with each set pre-loaded into separate delivery instruments. Each set is composed of one elliptical-shaped intravascular clip and two extravascular clips. Anastomosis is achieved by first creating an anastomotic port in the graft vessel by deploying the first set of clips through a small (4–5 mm) incision. After the first port is created, the second port is made on the target coronary artery through a 4–5 mm incision. In both anastomotic ports, the intravascular clip lies beneath the incised tissue while the two extravascular clips lie on either side of the intravascular clip outside the vessel. The conjunction of both ports creates an instantaneous coupling of them mediated by magnetic attraction, creating the anastomosis [15,16].

## Hypothesis

We hypothesize that we could reduce the risk of early and late recurrence of dissection by excluding the fragile aortic wall from the blood stream and avoiding surgical stitches directly on aortic dissected layers. We also hypothesize that confining the aortic tissue between the two prostheses could shorten operational time and help in the process of sealing and healing of the thoracic aorta. This concerns the distal anastomosis, that is directly involved in maintaining chronic aortic dissection. Proximal anastomosis at the level of the conserved or replaced aortic root is sutured upstream of the double prosthetic tube, therefore it cannot directly generate distal chronic dissection.

We here illustrate a new prototype of a double prosthesis consisting of:

- an inner and an outer prosthesis that enclose the distal stump and the aortic wall;
- sutureless sealing lines secured by means of neodymium magnetic bands.

The dissected aortic wall is kept outside the direct blood flow, which runs through the inner prosthesis, avoiding pressure stress and favoring sticking of the two lumina. Magnetic bands, specularly set in both inner and outer tubes, keep together the enclosed