

# Developments in instrumentation:

## II. Mechanical vascular anastomoses

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Minimally invasive surgery is rapidly replacing classical open surgery because the reduced trauma leads to a lower mortality, a quicker recovery and lower costs. Patient preference is also not surprisingly an increasingly important issue. Progress in vascular surgery in particular and other procedures where suturing is required has been slower because of the difficult execution resulting from the current laparoscopic suturing techniques. For this reason there has been considerable interest in trying to develop less exacting anastomotic techniques. Any method intended as a replacement for suturing must be widely applicable, produce equivalent or improved performance and be cost effective.

The completed anastomosis should be smooth, and provide strength and sealing characteristics equal to or better than those provided by sutures. Any technique or device should also produce an anastomosis which is safe and allow easy connection between host tissues and artificial graft materials. An improved clinical result should follow if these objectives can be met with minimal tissue manipulation. If the technique or device also permits more rapid execution than conventional suturing, then there is a significant potential for a significant reduction in surgical morbidity as the duration of aortic clamping is a major cause of mortality and morbidity and has a significant impact on the management of arterial and venous disease. Since the use of a mechanical device materially shortens aortic occlusion time, this has the potential

for lowering complications after a shorter surgical procedure, thereby improving the surgical management of various aortic, arterial and venous diseases. These advantages may result in a significant reduction in the overall surgical morbidity and may well facilitate the move towards total laparoscopic aortic replacement or bypass.

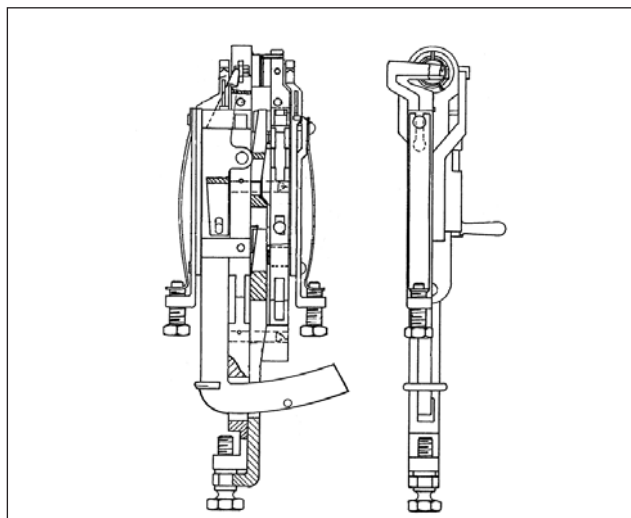
In coronary surgery these devices have radically reduced the time taken to perform an anastomosis and eliminated the need for aortic clamping and cardiopulmonary bypass in CABG (Coronary Aortic By-pass Graft) procedure.

Today, there are 236 (from 43 835 782) international patents and patent applications connected in some way or another with vascular anastomosis. Until now, in spite of numerous filed patents there is no vascular stapler on the market! This fact illustrates the complexity of the task – development of mechanical vascular anastomotic device permitting easy construction of a safe and durable anastomosis between aorta/artery/vein and synthetic graft, at least as good and safe as a hand-sewn anastomosis.

### Use of staplers

In 1950s, Androsov<sup>1</sup> reported on the use of a circular stapler, developed by Gudov et al., to create an end-to-end vascular anastomosis (Fig.1).

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Stapling device of Gudov comprising two parts each holding half a plug (different diameters); one part contains a plug with staples and the other serves as a support for bending staples; vessels from both ends must be reverted on these plugs and fixed

Fig. 1

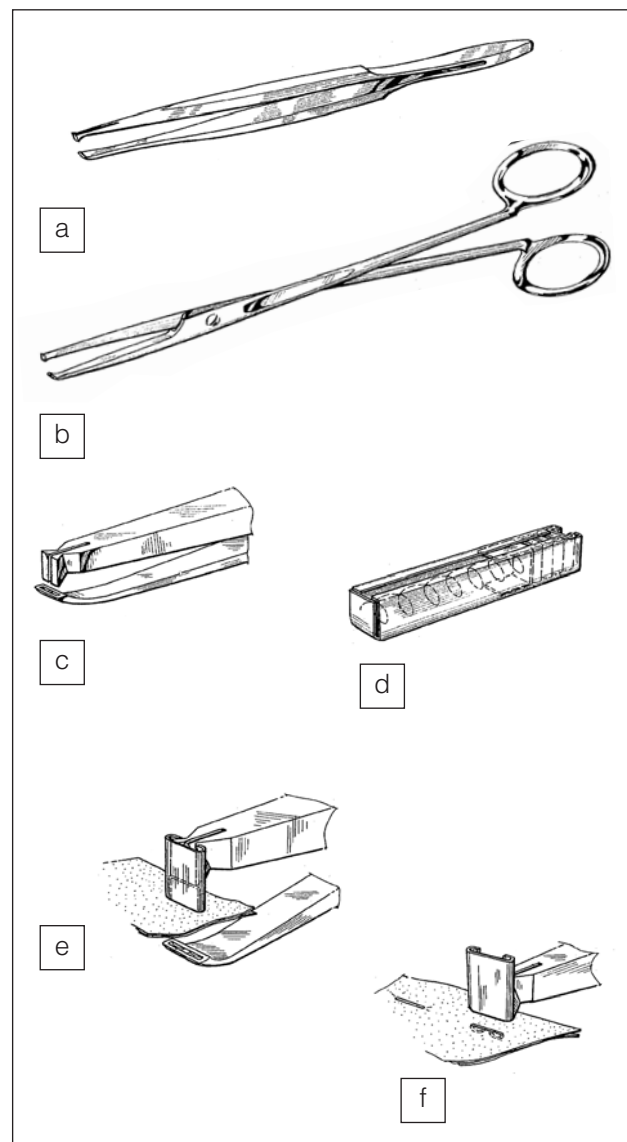
Rygg<sup>2,3</sup> in the 1960s introduced the use of staples for prosthetic valve fixation and for closing vascular incisions (Fig. 2).

In the same decades ('50-'60) Inokuchi<sup>4,5</sup> developed a stapler for vascular anastomosis, used in experimental surgery by de Donato et al<sup>6</sup>.

None of these devices gained wide acceptance because of the complexity of their use and the progress made by sutures, which proved to be cheaper, simpler and equally effective.

In 2005 a vascular stapler ("Datascope") with diameters of 16, 18 and 20 mm was presented to vascular surgeons. This device, defined as a stapling handle, consisted of an anvil, docking pin and handle trigger, positioning wand with guide wire and anti-recoil system. Fixation of the device with the graft inside the aorta is carried out by the application of a loop made of shape memory alloy strip. It is generally agreed that the use of this stapler is very complicated and time consuming (Fig. 3).

In 2000s, Shifrin and colleagues (ES Vascular Ltd., Israel) developed several types of vascular staplers for open (Fig. 4), laparoscopic (Fig. 5) and endovascular aortic-arterial-venous surgery, permitting mechanically stapled fast attachment between aor-

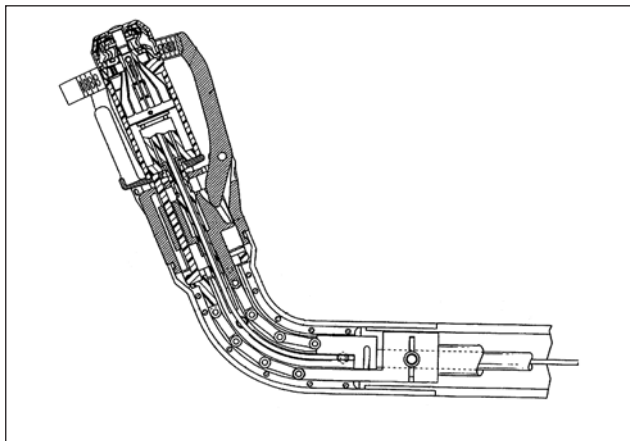


Principles of Rygg suturing device: a) clamping mechanism in a tweezer-like form; b) another clamping mechanism shaped as pliers; c) outermost end portion of one of the legs of the pliers; d) a magazine of staples; e,f) two steps of applying a staple suture

Fig. 2

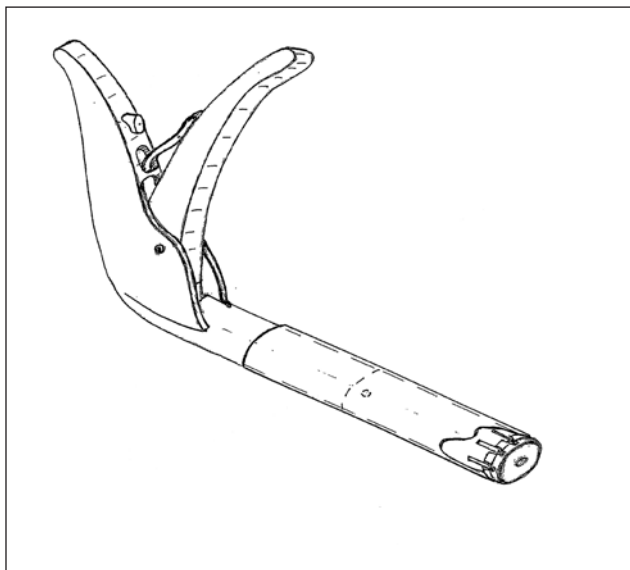
ta/arteries and different synthetic grafts. The aortic stapler device, including the laparoscopic version, consists of two parts, the head and the handle. The head of the stapler contains a 10-clip cartridge with a circular set of clips. The special feature of the clips is that they open on both sides, so that every clip

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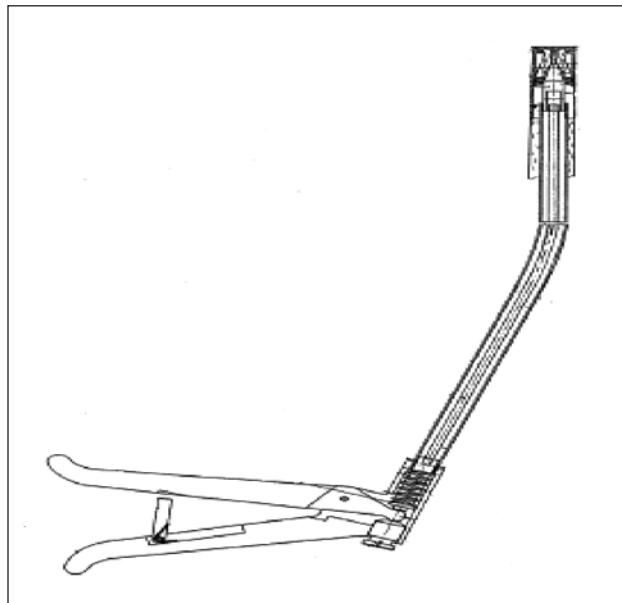
Datascope Aortic Stapler (Fontayne's device). The system contains a series of sizers, a specially designed graft, a loading unit, a wand, a surgical loop and a stapling instrument. The stapling device includes a plurality of anvils to form a circle and a trigger mechanism for firing the staples, deployed radially, which return on the anvils

Fig. 3



ES Vascular stapler for aorta-graft anastomoses. A stapler comprises a hollow body with mounted guiding head, a handle and a control lever connected to a tip located inside the head; additional pushing members are movably mounted in radial slots of the die; graft is fixated to aortic wall with 10 staples via set of at least two staplers (one for each anastomosis)

Fig. 4



ES Vascular laparoscopic aortic/arterial stapler. A stapler comprises a tubular body at the proximal end; there is mounted a head with die and die lid, and at the distal end a control mechanism with a retaining handle and a control lever connected via a spring-loaded pressure rod with a fastener means located in the die

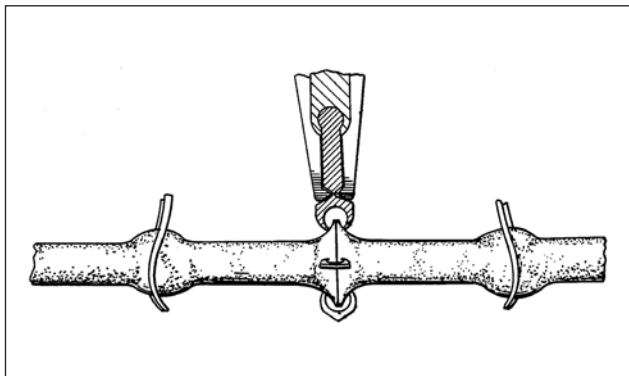
Fig. 5

fixes the graft to the aortic wall at two points. Also provided with the stapler are commonly used and approved grafts, which have to be mounted on the stapler, and a specially developed clamp to grip the aorta externally during the stapling process.

## Use of clips

In 1992 Kirsch et al.<sup>7</sup> introduced the principle of flanged, intimal approximation for microvascular reconstruction by the application of interrupted arcuate-legged, non-penetrating clips (Fig. 6).

To date, successful clipped anastomoses have been performed clinically in both the peripheral<sup>8</sup> and coronary circulation<sup>9</sup>. The ease of application of these clips was demonstrated with a short learning curve. They provide good conditions for vessel wall healing without excessive inflammation or fibrosis preserving endothelial function and are considerably quicker to use than sutures<sup>8-11</sup>. The main



End-to-end microvascular anastomosis with Kirsch's clip and applicator: approximation of partially everted edges of suturing vessels with clips placed over the edges with the arms of clips astride the point of apposition and without penetration of the intima

Fig. 6

disadvantage of these clips is their limited usefulness in atherosclerotic vessels, as the vessel wall has to be everted to complete the anastomosis<sup>10</sup>. They are currently available in various sizes (VCS clips; Auto Suture, Norwalk, CT, USA) and can be used for vessel sizes between 1 mm and 4 mm.

To facilitate eversion and to apply the clips circumferentially by a single maneuver, a one-shot anastomotic stapler (One-shot; US Surgical Corporation, Norwalk, CT, USA) has been developed. This device has been tested in animals and human cadaveric tissue for peripheral and coronary applications (proximal and distal vein graft anastomoses), with vessels as small as 1.8 mm in their outer diameter<sup>12</sup>. In a study on coronary vessel application performed in 14 pigs, Heijmen et al.<sup>13</sup> reported six out of 14 imperfect anastomoses because of clip malpositioning with respect to the vessel cut edges, manifestation of early endothelial denudation (2 days), and medial damage in both the coronary and distal internal thoracic artery (ITA), with two local dissections. All anastomoses remained patent at 4 weeks follow-up.

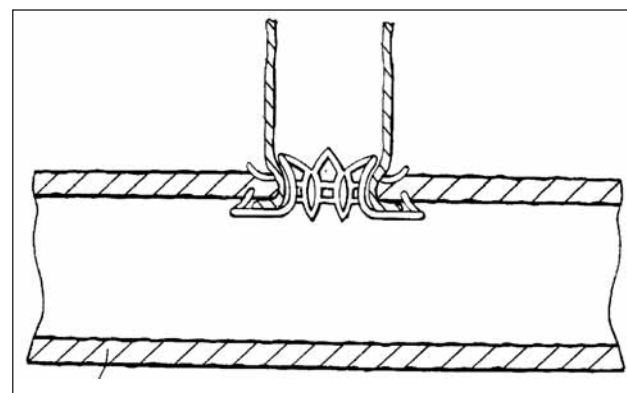
An excellent review of Falk<sup>14</sup> on proximal anastomotic devices in coronary surgery is currently published.

The development of proximal anastomotic devices was triggered by the evolution of Off-Pump CAB (Coronary Aortic By-pass). Since clamping of the aorta was no longer required to induce cardio-

plegic arrest, the next logical step was to avoid manipulation of the aorta altogether by inserting vein grafts into the ascending aorta without partial clamping, known for its potential risk for atherosclerotic embolization. Most proximal connector designs are based on expandable stents, which connect the graft to the aorta without the need for aortic clamping.

The Symmetry™ Aortic Connector System (St Jude Medical, MN, USA) uses a nitinol stent to connect the vein graft to the aorta (Fig. 7).

The saphenous vein is placed over a transfer sheet and loaded onto the delivery system, which is selected according to graft diameter. The hooks of the connector penetrate the wall of the proximal (aortic) end of the graft to prevent graft dislocation. After creating an aortal hole using a rotating blade, the actual delivery is performed. This process can be accomplished in a few seconds. Due to the design of the device, the proximal anastomosis has to be performed first and comes off the aorta in a 90° angle. This design intentionally reproduces the take-off of the native coronary arteries out of the aortic root. The CE Mark and FDA approval were issued in May 2001, and according to the manufacturer more than 80 000 devices have been implanted worldwide. With more widespread use, some conflicting reports concerning patency results were documented in the literature. The FDA also filed



Principle of St Jude's anastomotic device. A connector, providing an anastomotic connection between two vessels, has axial spaced portions that include members that are radially outwardly deflectable from other portions and engage both vessels connected at anastomosis; the apparatus has a delivering and deploying connector system

Fig. 7

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reports of early device disconnection. While initially there was great enthusiasm, reports of early graft stenosis and occlusion finally led to the withdrawal of the device from the market.

The PAS-Port System (Cardica Ltd.) is a one-shot device for proximal vein graft anastomosis to the aorta. It can be used for grafts of a diameter ranging from 4 to 6 mm (Fig. 8). For loading of the graft, the vein is pulled through the stainless steel implant and then manually everted over the end with the help of a poke-through tool; the everted vein is then attached to the implant. The deployment tool is placed on the aorta and the anastomosis is completed by a rotational movement at the end of the device. As with the Symmetry device, the proximal anastomosis has to be performed and the take-off angle is also 90°. Due to its design, there is no direct contact of the device within the bloodstream. The results of a multicenter trial with the first-generation device were quite promising.

The CorLink™ automated aortic anastomotic system (Cardioventions, NJ, USA) is a self-expanding nitinol extraluminal device (Fig 9). The graft is pulled through the inserter and then everted over the distal end of the delivery system. The everted segment of the vein is penetrated by five intimal pins that are deployed from the cartridge of the delivery system. A hole in the aorta is created by a

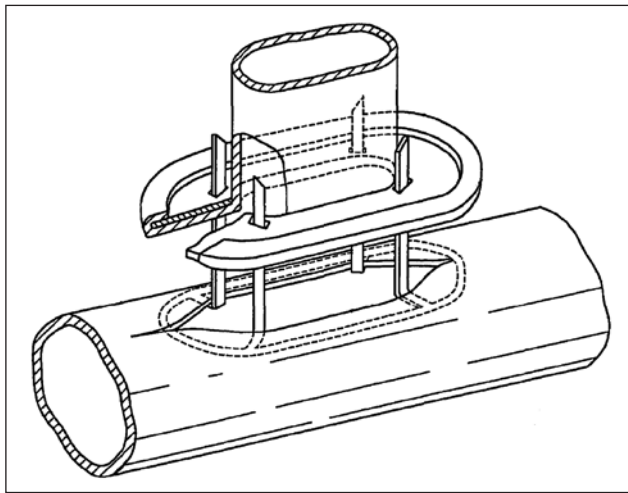


Fig. 8

Cardica proximal anastomotic device is an anastomotic stent of different diameters for connection of large (aorta) and small vessels (coronary artery)

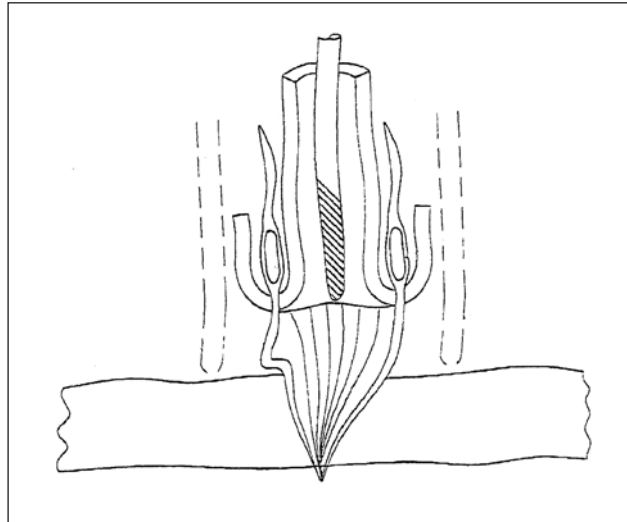


Fig. 9

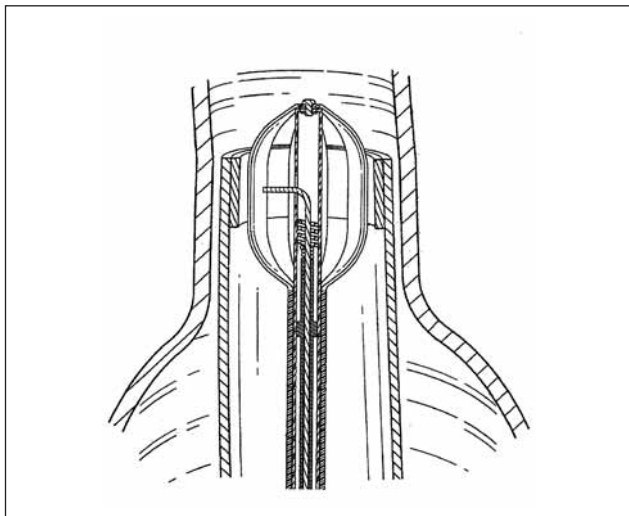
CorLink anastomotic device. An anastomotic connector for attaching two blood vessels comprising a cylinder-like portion and tissue engaging portion where at least one spike adjacent one of the two ends of cylinder-like portion; the connector may comprise at least a second set of spikes adjacent the other of the two ends

punching instrument that is inserted through the handle of the delivery system. Thus, as opposed to the Symmetry system, this device provides the arteriotomy device and connector in the same delivery mechanism. After the aortic punching device is withdrawn from the handle, the delivery system is advanced into the aorta and the connector is released. The connection is made by partial penetration of the aortic wall by the inner pins, while the outer pins stabilize the graft externally to the aortic adventitia. Only limited data regarding the device are available.

Aptus Endosystems, Inc has number of devices for fixation of endovascular prostheses to arterial wall (Figs. 10 and 11).

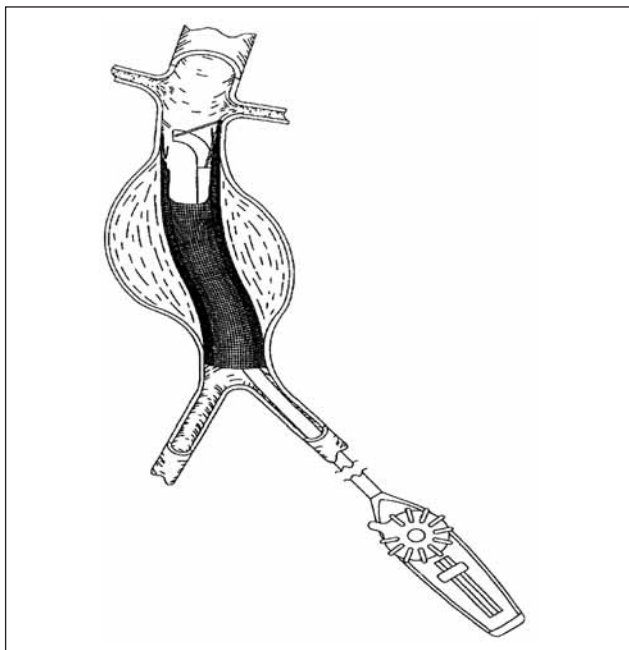
By-Pass Ltd has published two PCT applications, "Methods and devices for vascular surgery" and "Vascular port devices". The family of patent analogues for these patents contains about 140 patents. In spite of the "vascular" names of these devices they are intended only for coronary artery connections and do not have aortic applications. An analysis of these patents shows that they relate substantially to the construction of end-to-side anastomoses using a special apparatus for the delivery of

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Aptus endostapling device (Parodi). Systems and methods to apply a suture within a vessel lumen with catheter tube, and a suture applicator at a distal part, which is operated from a location external to the blood vessel lumen, to apply a suture to an interior wall of a vessel

Fig. 10

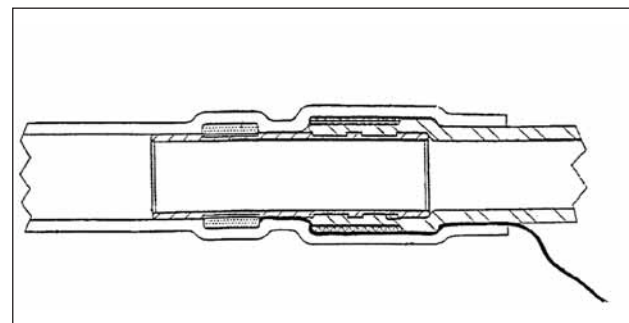


Aptus endostapling device. It provides permanent attachment of endovascular prosthesis, which can be deployed without damaging native vessel using fastening system through the vasculature, and manipulated from outside the body to deliver a fastener to attach the graft to the vessel wall

Fig. 11

mostly autografts, taken from the same patient. The graft is inserted into the axial duct of a special split sleeve ("butterfly" member), flanged at one end on the end of this split sleeve and fixed in this position using a special nitinol fastener. The whole structure is located and secured in the axial cavity of a delivery apparatus (substantially the apparatus designed by Ethicon) which serves for graft delivery to the location of the anastomosis, punching the blood vessel wall at the I anastomotic site and securing it to the opening edges via a nitinol fastener. (Fig. 12).

The comparative analysis of all these devices with Shifrin's aortic stapler showed that they are totally different and incompatible with one another. In fact, the By-Pass apparatus itself is used substantially for creating an end-to-side anastomosis. The diameter of the grafts used ranges from 0.8 to 6-8 mm. The graft is inside and secured to the vessel in an outside to inside direction. In Shifrin's aortic stapler a graft is placed and secured outside the working head and then in the anastomosis area as well via stainless steel staples. The apparatus is designed to execute an end-to-end anastomosis between aorta and synthetic prosthesis in direction from the graft from inside the vessel. The device diameter ranges from 9 to beyond 22 mm. Thus, in conclusion, the apparatus described above: a) has different, quite specific, applications; b) solves different tasks; c)



By-Pass Vascular Port Device, a non-suture anastomosis system for securing a bypass graft to a host vessel; a compression mechanism is used with the system for attachment of the bypass graft to the fitting; an electrode is connected to the fitting and to an energy source which transmits energy to the electrode, which, in turn, causes the adjacent tissue to rise temperature and bond to a vessel or fitting

Fig. 12

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performs different functions; d) uses novel fastener staples fabricated from stainless steel.

All these devices may be regarded as complementing each other in the context of their use in cardiovascular surgery.

As already pointed out, the different anastomotic devices described in this field and available in the patent literature meet some or most but not all the requirements for safe and efficient anastomotic vascular surgery<sup>15</sup>.

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