

## **Endovascular Treatment of Abdominal Aortic Aneurysms**

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Modern treatment of abdominal aortic aneurysms began in Paris in March 1951, when Dubost performed the first successful aortic resection for aneurysm (1). Abdominal aortic aneurysm (AAA) is a relatively common disease among the elderly population, reaching a frequency in the overall population of up to 36.2 cases per 100,000 population (2), and may be present in up to 5.9 % of the population aged 80 years (3). AAA with more than 5 cm in diameter are more prone to rupture. Rupture is related to significant mortality of up to 63 %. Conventional surgical repair of AAA, in patients with low or acceptable surgical risk, is quite effective, with a morbidity and mortality rate ranging from 0 % to 8 % (4). However, in the population in the "risk level 3" of the SVS/ISCVS Medical Risk Factor Categorization table (Table 1), the mortality ranges from 8 % to 60 % (4). In view of the persistent morbidity and mortality with conventional surgical repair of AAA, specially in the population at higher risk, there was an increase in the necessity for development of a less invasive and potentially safer techniques of treatment using endovascular stent-grafts. Vascular endoprostheses were developed in an attempt to avoid major conventional surgical repair for AAA.

Developed about 10 years ago, the stent-grafts for repair of AAA already have a fascinating history which is full of agony and ecstasy. A intraluminal stent-graft device consists of a supporting frame covered with a synthetic graft material. Parodi in 1976 began to develop the concept of endovascular graft treatment of AAA and performed several unreported animal experiments (5). Balko et al., in 1986 introduced the first intraluminal prosthesis with a self expandable Nitinol frame covered with polyurethane (6). The device was used acutely in a sheep model with success. Mirich et al., in 1989, reported on an endoprosthesis using Gianturco Z-stents covered with Nylon, which was used in a mid/long term animal model with successful exclusion of aortic aneurysms (7). Parodi in 1990 performed the first human stent graft placement for treatment of AAA (5), backed up by extensive animal experiments (8). The device developed by Parodi was balloon expandable and used a large size Palmaz stent, stitched to a Dacron graft tube. At that time it was not immediately recognized that the distal neck needed to be also stented and a few patients presented with significant

endoleaks due to faulty sealing at the distal attachment, requiring further treatment with an additional stent placement. Although successful, the Parodi device was technologically limited and useful only to a few patients. With the development of the bifurcated devices, patients with AAA without a distal neck, presented with the opportunity to be treated. The Lazarus device, the first bifurcated stent-graft had an US patent issued in 1988 (9). It was an unsupported system and was used in humans for the first time in US in 1993 in a tube configuration, and was known as the EVT device (10). The first self-expandable, supported, bifurcated stent-graft, the Stentor system, was developed in Europe and used in humans for the first time in 1994 (11). By 1993 other custom made devices were already in use, such as the Ivancev-Mälmo device (12) and the Chuter device (13). Those were aorto-uni-iliac devices and required occlusion of the contralateral iliac artery, and a femorofemoral bypass. By 1994 the modular concept was already in evolution with the AneuRx device (14). The Talent device became available for trials, as a customized, bifurcated device, enlarging the pool of patients amenable to be treated (15). In 1995-1996 the EVT device presented with metallic attachment system fractures in 23% of the implants, which led to temporary suspension of the program until the defect was corrected. In 1997-1988 some of the first patients treated with the Stentor device in Europe presented with signs of material deterioration and several incidents of device failure resulting in late leaks and AAA rupture (16-18). In 1999, Resch and Ivancev reported on several cases of distal migration of stent-grafts apparently due to a surprising, continuous dilatation of the proximal aneurysmal neck, in cases where the first generation device was used (19). In 1999, the EVT device, now known as Ancure, and the AneuRx device, were approved by the FDA and became commercially available in the US. Recently, cases of AAA rupture after endovascular repair using the AneuRx device were reported (20). The remaining devices are still undergoing trials in US and it is expected that a number of other stent-grafts will be FDA approved by the years 2000-2001.

The treatment of AAA with stent-grafts is a rapidly evolving field and the information available changes overnight. We would like to review and present some current aspects of the endovascular treatment including the different types of available devices, design and classification of the devices, potential problems and complications as well as the management of some of these problems and preliminary results and outcomes.

### **Design and Classification of Stent Grafts:**

Desired characteristics of the stent-grafts for AAA are related to low profile, adequate flexibility, kink resistance, longitudinal strength, easy and precise deployment, reliable fixation system, low permeability of the graft fabric, ability for crossing the renal arteries without obstruction, and modularity for customization of limb length. Obviously, no ideal device is available at this moment, not only because it is hard to find all the characteristics in a single device, but also

because most of the different features are protected by specific patents which are property of different companies.

The earliest stent-graft designs were unibody and for use in a tubular configuration, such as the Parodi device. Later, the bifurcated unibody design was developed, resulting in an unsupported device with a relatively complex delivery technique.

The modular device was the next step of development, and is currently the most popular configuration of the endovascular devices available for AAA repair. Modularity allows for lower profiles, increased flexibility with increased kink resistance. In modular systems, the contralateral limb is deployed in a retrograde fashion, requiring selective catheterization of the short leg of the main device section from the contralateral femoral artery. An extraordinary feature of the modular systems is the availability of cuffs and extenders that are used to improve the fitting of the device to the patient's anatomy and to fix endoleaks.

Currently all modular devices are supported with increased kink resistance, while the unsupported devices are more prone to kink and become compressed by progressive atherosclerotic disease. Supported walls, however, means a supporting skeleton, usually metallic, which increases the profile of the device, requiring larger iliac arteries for access.

There is still great discussion about the need for fixation mechanisms at the proximal neck, and some devices use small hooks to anchor the proximal end of the stent-graft into the aortic wall. Most devices use the radial force of the proximal stent for fixation in addition to barbs and hooks, and some devices use the expanding radial force of the stent, plus the friction of the device surface as the only method of attachment.

## **Technical Aspects of Endovascular Repair of AAA**

Successful endovascular repair of AAA is a multidisciplinary effort, with participation of several specialties. The contribution of each discipline is variable according to the institution, but usually involves a surgical team for the performance of the cutdown techniques and access management and an interventional radiology team for the performance of the catheter/guidewire techniques. The contribution of an anesthesia team, familiar with the procedure, is key for the safety of the procedure. Currently most procedures are performed with epidural anesthesia and conscious sedation reducing the overall length of hospitalization (21). The need for high quality fluoroscopic imaging during the procedure should not be underestimated for the success of the program. Compulsive preprocedural imaging including CT and invasive angiography enhances the selection of patients, improving the final results. Careful postprocedural imaging with contrast enhance helical CT, for evaluation of

aneurysm sac perfusion, graft patency, changes in diameter of the vessels and aneurysm morphology is an essential part of the treatment.

All currently available devices require a femoral cutdown technique for introduction of the delivery system and stent-graft placement. Knowledge of meticulous surgical technique and preservation of the flow to the lower extremities is mandatory for the success of the procedure. More extensive femoral and iliac arteries dissections are necessary in diseased and tortuous vessels. The liberation of the external iliac artery is specially important in cases of severe tortuosity, when traction of the artery will improve the access for the introducer system, specially the larger ones. In most patients a more conservative cutdown is possible with minimal arterial exposure. Some devices such as the AneuRx device and Vanguard have a small enough contralateral extension that allows a percutaneous approach or a more conservative cutdown technique. The Quantum stent-graft was designed for a bilateral femoral percutaneous approach, but is not available outside the phase I trial in US.

Knowledge and experience with catheter/guidewire based techniques for the manipulation and precise placement of the device is essential for a successful stent-graft program. One of the most challenging aspects of the procedure is the deployment of the device at the level or below the level of the renal arteries, preserving the kidney perfusion. The second most challenging phase of the procedure is the contralateral approach and catheterization of the short limb of the main device within the aneurysmal sac. Precise placement of the extensions in both sides, preserving the flow into the internal iliac arteries, is another important step of the procedure. Final evaluation of the device placement with angiography and CT angiography is very important for verification of the success of the procedure and to improve outcomes.

### **Outcomes:**

Exclusion of the aneurysmal sac is the main goal of the stent-graft treatment, and clinical success is defined by “total exclusion” of the aneurysm. Persistent flow of blood (or radiological contrast, for that matter) into the aneurysm following stent-grafting is called “endoleak” and is classified by cause and time of occurrence. Endoleaks cause continued pressurization of the aneurysm sac, indicating a failed procedure, and may leave the patient at risk for AAA rupture, if not resolved or untreated. Most AAAs when treated by the endovascular techniques should stabilize or shrink.

### **Endoleak**

Endoleak is a condition unique to endoluminal vascular grafts defined by the persistence of blood flow outside the lumen of the endoluminal graft but within an aneurysm sac or adjacent vascular segment being treated by the device (22).

Endoleaks are due to incomplete sealing, or exclusion of the aneurysm sac or vessel, and/or reflux of blood flow into the sac, as demonstrated by some form of imaging studies.

Four types of endoleaks are currently recognized. A distinction is made between endoleaks related to the graft device and unrelated to the graft (22).

**Type I Endoleak** - This type of endoleak occurs when a persistent channel of blood flow develops due to inadequate or ineffective seal at the graft ends. This type of endoleak is usually present early in the course of the treatment but may also be encountered late when blood erodes through a blood clot seal around the area of device fixation to the aortic wall.

**Type II Endoleak** - This is a retrograde type of endoleak. It occurs when there is persistent blood flow into the aneurysm sac due to retrograde blood flow from patent lumbar arteries, the inferior mesenteric artery, or other collateral vessels. In some circumstances when there are two or more patent vessels a situation of inflow and outflow develops creating an actively blood flow within a channel created within the aneurysm sac.

**Type III Endoleak** - This type of endoleak is related to inadequate or ineffective seal at the graft joints, between segments of overlapping graft segments, or rupture of the graft fabric. This type of endoleak may develop early, due to technical problems or late in the course of the treatment when there is displacement of one of the extensions due to aneurysm retraction or device breakdown.

**Type IV Endoleak** - This type of endoleak is related to the porosity and passage of blood through the fabric of the graft. Since the grafts used in endovascular devices are not preclotted most fabrics will initially leak through. With the development of thinner graft materials this type of endoleak is becoming more common.

**Endoleak of Undefined Origin** - This type of endoleak has an unknown cause and location, which may be eventually defined as the imaging techniques get more refined.

**Endotension** - Condition when high pressure may be maintained within the aneurysm sac with no evidence of leak or blood flow outside the graft. One proposed mechanism is pressure transmission via thrombus that lines the attachment site. Endotension may also represent an indiscernible, very low flow endoleak that allows blood to clot at the source of leakage (23). Also known as "Endopressure" or "Nonendoleak aneurysm sac pressurization".

Classification of endoleaks is an evolving proposition and further specificity can be gained by adding the qualifiers A or B, where A refers to endoleaks in which

only an inflow channel can be demonstrated and B refers to endoleak with apparent inflow and outflow channels. Endoleaks can be also called primary (early) or secondary (late) (22).

### **Treatment of Endoleaks:**

Patients developing an early endoleak, within 30 days, should be treated by a period of observation and secondary endovascular intervention in persistent cases. Patients developing a late endoleak should be treated similarly, without a period of observation (24).

Type I endoleaks can be treated by different means including: Repeated and more aggressive balloon angioplasty of the attachment related to the leak. The irregularities of the proximal neck may sometimes be minimized by balloon angioplasty before placement of the device, however, it has not been proved to reduce the leaking rates. Placement of extenders at the proximal neck or distal landing areas of the graft are effective ways of controlling Type I endoleaks, by the additional coverage at the end of the graft and the extra radial strength of the extender sealing off the leak. Embolotherapy with coils, thrombin and particles is also effective in selected cases (25,26) but selective catheterization of the endoleak tract is necessary, which may be not always feasible.

Type II endoleaks treatment is a more complex issue. First, there is intense debate whether it is necessary or not to perform prophylactic embolization of a prominent branch of the aorta, such as the inferior mesenteric artery or lumbar artery, connected to the lumen of the aneurysm. We occasionally proceed with embolization of a prominent IMA (Fig. 1 – Figures are located at the end of this article in the Legends section), or lumbar artery embolization if there is patency of a prominent or multiple large lumbar arteries (Fig. 2) before the procedure. Second, there is also discussion on the opportunity of treating a persistent retrograde blood flow from an aortic branch into the aneurysm sac, following stent-graft placement. It seems that unsupported grafts are more prone to present Type II endoleaks due to the increased flexibility of the graft wall and continuous changes in volume of the aneurysmal sac with the cardiac cycle. Embolotherapy of a persistent patent branch with retrograde flow, when it becomes necessary, is an effective way of treatment. Embolization of a patent lumbar artery, usually can be accomplished by superselective catheterization of the iliolumbar artery with a microcatheter and embolization with particles or microcoils via the iliolumbar artery (27) (Fig. 3). The IMA can also be embolized from an “outside-in” approach with superselective catheterization with a microcatheter, from the superior mesenteric artery, through the middle colic artery, arch of Riolan and marginal artery, with deposition of coils into the aneurysmal sac and at the main segment of the IMA (28). In some instances it is also possible to break the seal of the proximal or distal attachments of the graft and reaching the perigraft space and do an “inside-out” approach with selective

embolization of a lumbar artery or the IMA (Fig. 4). Alternatively, when the intraarterial approach fails or is not feasible, the endoleak tract, within the aneurysm sac can be embolized by a translumbar approach with direct embolization of the tract with thrombin and Gelfoam (Fig. 5). Laparoscopic treatment of Type II endoleaks has been recently proposed by some authors (29).

Type III endoleaks can usually be treated by balloon dilatation of the junction between the two components of the stent-graft. The placement of an additional extensor or a cuff at the level of the leak may be necessary and is probably more effective, when there is rupture of the integrity of the graft fabric. When the appearance of a Type III endoleak is delayed, or develop over a longer period of time, due to device migration or kinking, the use of a cuff is mandatory, but may not be as effective, depending of the degree of separation and angle between the device components. The use of a bare metal stent has been used successfully to repair junctional stent-graft leaks (30). When the endoleak is due to perforation of the graft material, the only endovascular treatment option is the placement of covered segments (extenders) of the stent-graft within the damaged segment (Fig. 6). However, in some cases, surgical conversion is the indicated treatment.

Type IV endoleaks do not usually need treatment. Since it is related to the porosity of the graft material, which is not preclotted, there will be spontaneous sealing of the fabric by clotting within the aneurysm and within the fabric material in the large majority of the cases. Use of anticoagulants and antiplatelet adhesion drugs should be avoided during this period of time.

Supplementary endovascular intervention to treat endoleaks is an important adjunct to endoluminal AAA repair with the potential to improve outcome and avoid conversion to open repair. Successful supplementary endovascular intervention may be achieved in 85% of patients in whom it is attempted. Life-table analysis showed supplementary procedures to be durable in the long term, in a recently published series (24).

## **Outcomes and Complications of Stent-grafts for AAA:**

Aortic stent-grafts can be successfully inserted in more than 90 % to 95 % of properly selected patients. The most common cause of failure is the inability to insert the device through a severely diseased and/or tortuous iliac artery. Misplacement of the device or migration during the deployment, are rare but severe complications, requiring surgical conversion to an open procedure. A rare but possible ischemic complication of the device placement is neurologic damage to the cyatic nerve in cases of occlusion of the internal iliac artery associated to a more extensive dissection of the external iliac artery. The endoluminal repair of AAA results in less respiratory and hemodynamic stress to the patient, when

compared to conventional surgery. Blood loss is lower in the endoluminal repair, than in conventional surgery, and the use of intensive care unit and hospital stay is significantly reduced.

The EUROSTAR registry is currently the most reliable source of information on outcomes and complications of the treatment of AAA with stent-grafts because it includes a large cohort of patients (31,32). The European reports are usually based on the operative risk classification of the American Society of Anesthesiologists (ASA), while the American reports in general use the medical risk categorization table from the SVS/ISCVS (4). According to a recent EUROSTAR report, operative complications could be grouped into three categories: Failure to complete the procedure, 2.5 %; Device related or procedure related complications, 10 % and Arterial complications, 3 %. The incidence rate of systemic complications within the first 30 days was 18 %. Mortality within 30 days after operation was 2.6 % (31). Observed technical success ranged from 72 % to 82 % in the EUROSTAR report. Other reports on specific devices present technical success of 85 % to 96 % (10,11,14,15,33) .

Complications of endovascular treatment of AAA may be related to the device or procedure, during the operative period, or within 30 days of the procedure. Identified, procedural and within 30 days complications are: graft-limb thrombosis or kinking, peripheral embolization, local hematoma or bleeding, failure to advance the device into deployment position, vascular laceration, occlusion of renal artery, internal iliac artery causing pelvis ischemia, device migration, AAA expansion and rupture. Additional, within 30 days, complications are more systemic in nature and usually related to organ failure. Later complications, after the 30 days period, are less common, but are more frequently related to peripheral vascular occlusion, device disruption/migration and aneurysm rupture.

A common occurrence immediately following the procedure is the post implantation syndrome, characterized by fever, leukocytosis and elevated C-reactive protein levels.

## **Summary of the Devices:**

### **Ancure Stent-Graft (EVT/Guidant, Menlo Park, CA)**

The Ancure device was developed by the company EVT and now is produced and commercialized by Guidant. The first production endografts to enter clinical trials in US, was approved by the FDA in September 1999 for clinical use under a careful monitored training program. The Ancure is a bifurcated, non supported stent-graft with proximal and distal "hook like" fixation devices made of Elgiloy. The zigzag attachments are self-expandable but not strong enough to fixate the device to the aneurysm neck, requiring hooks for penetration of the aortic wall. The graft is made of Dacron with crimped legs. A tube version is available and

was the device used in Phase I study, in the US trial. Some fractures of the attachment devices occurred during Phases I and II of the trial but the problem has been corrected. The latest generation of the delivery system was redesigned and has been significantly improved. However, due to the design of this device, it is still one of the more complex to use. Since the legs of the bifurcated devices are unsupported, a significant number of patients develop kink or torsion of the leg extensions, requiring treatment.

The system is available for treating AAA with 20- to 26-mm in diameter, and the introducer is 27.5-French.

In the US trial, 538 patients were treated, with 90.3 % success rate in phase II and 96.3 % in phase III. There was a 29.8 % endoleak rate, 4.4 % type I and 25 % type II. There was a significant number of reinterventions and flexible stents were used to correct or prevent kinks in the legs in about a quarter of the cases.

### **AneuRx Stent-Graft (Medtronic, Sunnyvale, CA )**

The AneuRx stent-graft is a modular stent-graft with a Nitinol external skeleton with a Dacron graft inside, and connected to each other by about 1000 sutures. The device was originally designed and developed by the company Anorex and subsequently produced and commercialized by MedTronic. The device was approved by the FDA in September 1999 and is commercially available in US, although the supply does not meet the demand for the device at this time. The AneuRx device is easy to use, but the current available sizes limit the application of the system to a smaller number of cases. The main strength of the device is the modularity. In fact AneuRx introduced the concept of modularity, providing multiple cuffs and extensions to treat leaks and occasional malpositioning of the device.

The AneuRx device is delivered with a 21-French introducer, and released with a crank handle. The device was used in about 971 patients in the US during different phases of the FDA required trials, and was successfully placed in 97.6 % of the patients in the phase II trial. The one year endoleak rate was 20 %. A significantly larger number of patients had been treated with this device following the approval.

### **Quantum LP Stent-Graft (Cordis Corp., NJ)**

This is a bifurcated three piece device, which introduced the concept of a low profile Nitinol aortic gasket and two long extension legs. The device is deployed with a 13-French introducer in a percutaneous fashion. The extensions of the stent-graft are self expandable, with a frame of Nitinol and the graft is thin Dacron.

The Cordis stent-graft can be used in AAA with a proximal neck ranging from 14-

to 29-mm and iliacs of 12- to 16-mm in diameter. The phase I trial in US has been halted due to kinking and occlusion of the extensions, as of March 2000, to allow re-engineering and improvements of the device. Only 17 patients have been treated so far in US, Europe and Australia.

### **Endologyx (Bard )**

The Bard Endologyx device is a unibody self-expandable device, with a frame made of Elgiloy and graft of PTFE. The diameter of the proximal stent ranges from 25 to 28 mm and the introducer ranges from 20 to 21 French size. The contralateral sheath is 12.5 French.

Phase I trial is complete with about 96 cases, with 98 % success rate. Endoleak rate at discharge is about 4.4 %. Phase II is started.

### **Excluder Endograft (Gore and Assoc., Flagstaff, AZ)**

The Gore Excluder is a stent graft with a spiral frame of Nitinol covered in and out with PTFE sealed by heat. The device is wrapped around the delivery system and tied with dental floss like tread.

The open device proximal segment size, ranges from 23 to 31 mm in diameter and is introduced with an 18 French sheath. The extensions range from 12 to 16 mm in diameter and are introduced with a 12 French sheath. Initial European experience showed initial technical success rate of 100%. Primary endoleak rate was 12%, with only one case of secondary endoleak with 12 months of the procedure. The preliminary results of the Phases I and II US trials are not available at this point.

### **Lifepath (Baxter)**

The Lifepath stent-graft derives from the "White-Yu Device" is a combination of self-expandable with balloon expandable device, made with a metal frame of Elgiloy and stainless steel. The device ranges in diameter from 16 to 26 mm and is introduced with a 21-22 French device. The extensions are available in 10 to 16 mm in diameter and introduced through an 18 French sheath.

Phase I is on the way with 29 patients enrolled and 98 % success, as of this written.

### **Talent Stent-Graft (World Medical Inc. Sunrise, FL/ Medtronic, Sunnyvale, CA)**

The Talent stent-graft device is a custom made, supported, self-expandable, bifurcated device with a metal frame made of multiple Nitinol stents inside the main body of the graft and placed outside the leg extensions. In the latest available generation of the device the graft is made of thin Dacron (Low Profile

System, also known as LPS)

The body of the stent-graft ranges from 20 to 48 mm and is loaded in a 20 to 27 French introducer. The extensions are 8 to 20 mm in diameter and introduced with a 16 to 18 French device. An aorto-uni-iliac stent-graft is also available together with a contralateral iliac occluder. The main strengths of the device are the availability in a custom made fashion and the convenient bare stent (Free Flow) at the top end for transrenal placement.

Phases I and II, high risk trials are completed and a Phase II low risk study with the first generation device has been completed and a Phase II low risk study is underway with the LPS device. More than 400 patients have been treated in USA and more than 4000 patients were treated worldwide.

A preliminary report from US showed a 90% initial success rate with this device with one death within a week of the procedure in a high risk population (15). A more recent report from Europe presented a primary technical success of 83 % with an increased secondary technical success rate to 93 %, with two surgical conversions and a 5 % mortality within 30 days (33,34)

The results of the multiple trials with this device are variable due to the different populations treated. There is was a 92 % deployment success rate in Phase I (high-risk population) with exclusion of the aneurysm sac in 72 %. The 30 day technical success rate was 95 %. Thirty day mortality was 12 %. The phase II high-risk trial had a deployment success of 94 % and aneurysm sac exclusion in 80 %. At 30 days the technical success was 91 %, with a 30 day mortality of 1.5 %. Phase II low-risk trial included a first generation and a second generation device. Deployment success rate were 97 % and 99 % respectively, and technical success at 30 days were 91 % and 97 %. Thirty day mortality was 4 % for the first generation device trial, with an adverse-event rate of 20 %. Thirty day mortality was 0 for the second generation device and adverse-event rate was 1.8 %.

### **Vanguard II and III** (Boston Scientific Corp., Natick MA)

The Vanguard stent-graft (formerly known as the Mialhe/Stentor from MinTec Inc., France) is a supported, bifurcated, self expandable device, made of a frame of Nitinol covered by a thin Dacron graft material.

The device is 22 to 30 mm in diameter and introduced through a 21-French sheath. The extensions are 10 to 12 mm in diameter and introduced percutaneously with a 12-French introducer. There is a bare stent on the top end of the endoprosthesis which allows transrenal placement of the proximal end of the device. The use of a percutaneous contralateral approach is a significant advantage of this device.

Phase II trial is completed in US with about 243 patients enrolled. There was a 97 % success rate with about 19 % endoleaks. More than 4200 patients were treated worldwide with this device. Initial difficulties in using this device in Europe included lack of additional modular extensions and the limited availability of extensions lengths and diameters. Long term follow up of the first generation Mialhe/Stentor device showed some degree of late disintegration of the device in some of the initial patients, requiring surgical treatment. The device used in the US trial was an improved version called Vanguard, versions II and III, which proved to be more reliable. At this time the US trial has been halted until modifications in the introducer system are made.

### **Zenith Stent-Graft** (Cook Inc., Bloomington, IN)

Originally known as the Perth bifurcated aortoiliac stent-graft, the Zenith device is a supported, bifurcated, self expandable stent graft with multiple stainless steel Z stents placed inside the graft, with a proximal bare stent that can be placed across the renal arteries. The device is very modular and can be ordered with an extensive array of extension sizes and diameters. It is available in an aorto-uni-iliac configuration and a smart adaptor for conversion of a bifurcated device into an aorto-uni-iliac configuration is also available. There is a bare stent at the top end of the system, which allows for transrenal placement. The delivery system deploys the device from bottom to top and the bare stent at the top is delivered last.

The device ranges from 22 to 32 mm in diameter using introducer of 18 to 20 French sizes. The extensions range from 8 to 24 mm and are deployed through a 14 to 16 French sheath.

Phase II is underway in US and more than 2000 patients have been treated worldwide. Success rate is 87 %, with 6.2 % Type I endoleaks and 5.8 % Type II endoleaks.

### **Corvita Endovascular Graft** (Corvita Inc./Schneider Corp./Boston Scientific Corp. Natick, MA)

The Corvita endovascular graft was a cylindrical device with flared ends made of a Elgiloy alloy, self-expandable, double-wire braided stent with a liner of polycarbonate urethane microfibrils bonded together. The device was available in a basic tubular configuration and on a bifurcated configuration. The bifurcated module was crimped longitudinally in the anterior and posterior wall, and the inner lumen was divided in two channels by the polycarbonate urethane liner, where the two extensions could be fitted.

Phase I trial in US was abandoned after several months with an undisclosed number of patients treated. In an European series with 153 patients treated the device was successfully placed in 96 % of the attempts, but presented many

problems including a 42 % rate of immediate endoleak and 14 % long term endoleaks. Late migration of the device was observed in 21 % of the patients. This device presented an unique problem related to changes in configuration to a cigar shape allowing for migration and leaks.

The introducer used an 18-French sheath through a femoral cutdown.

### **Anaconda Stent-Graft** (Sulzer Vascutech, Germany)

The Anaconda device is made of Nitinol covered with Dacron. Phase I is starting in US. Only a few patients have been treated in Germany in the last 2 years. The contralateral catheterization for placing the extension is performed with a magnetic device which facilitates the procedure. The preliminary results of this device are not available.

### **Ella Stent-Graft** (Ella-CS, Hradec Kralove, Czech Republic)

The Ella stent-graft is a self-expandable supported device with a frame of stainless steel covered by thin Dacron graft. The metal frame is flexible and the multiple metal springs are connected by an ingenious system of hinges that provides flexibility to the device. Currently the device is available only in the aorto-uni-iliac version using an occluder for the contralateral iliac, but a bifurcated design is said to be available soon.

This device has been used in more than 100 patients, mainly in Eastern Europe. There are no prospects for a trial in US, at this time. The results of the initial experience in Europe are not available at this time.

## **Future and Possible Developments in Endovascular Repair of AAA:**

The stent-graft repair of AAA is an evolving procedure with rapid clinical popularization throughout the world. The technology available is changing the procedure and improving the results of the treatment on a month by month bases. Several key questions on the efficacy of the devices and the long term results of the technique are still unanswered..

Persistent perfusion of the aneurysm sac through side branches is still an unsolved problem, and ancillary technique, such as the filling of the aneurysmal sac with a thrombogenic polymer or foam will be necessary to be developed in the near future. Other alternatives, such as the combination of endovascular techniques and laparoscopy may be necessary to be developed to help some patients (29).

Fixation of the device to the aorta might evolve into a technique using a stapler

device to replace the surgical suture of the conventional graft into the aortic wall. The endovascular construction of the device using separate parts, such as the supporting skeleton placed after the deployment of the graft, may further reduce the profile of the stent-graft allowing patients with smaller iliac arteries to be considered for treatment (35). The transrenal fixation of a proximal bare stent allows for a more secure fixation of the devices in patients with shorter proximal necks, when compared with devices designed for infrarenal fixation (36). Based on the current favorable results available, transrenal fixation is likely to become more popular in the future. The development of stent-grafts with side arms to accommodate major branches of the aorta is a potentially significant technical improvement, which may allow the treatment of patients with more difficult anatomy (37,38) The development of new and smaller devices will probably modify the traditional size threshold of 4.5 to 5 cm for repair of AAA in patients with low surgical risk.

Long term aneurysm exclusion is the goal of the endovascular technique, and despite the extremely encouraging early results with the endovascular treatment of AAA, it is still early to predict the future role of this technique. It is expected, however, that especially patients at higher risk will benefit the most from this less invasive technique.

**Legends:**

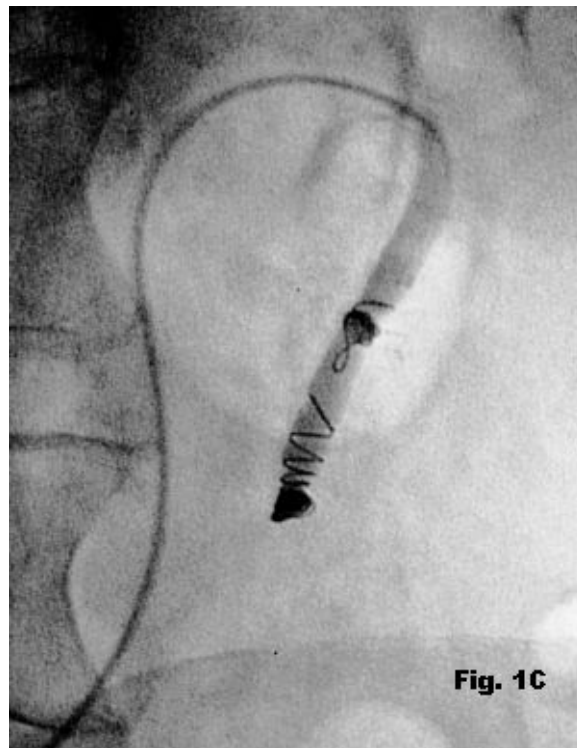
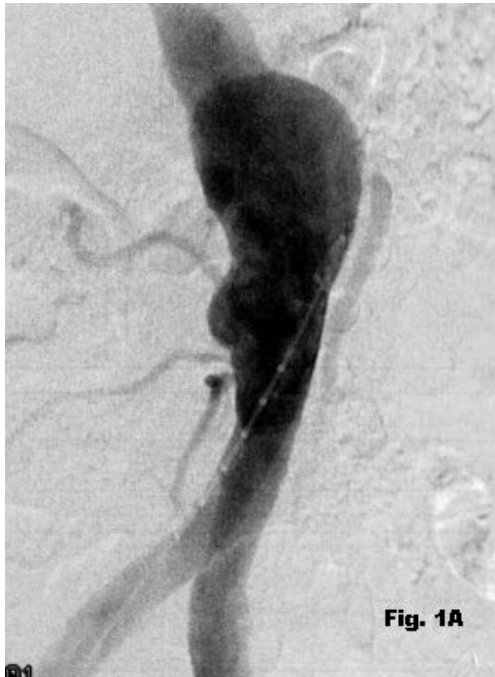


Figure 1. 73-year-old male patient with AAA presented with a prominent IMA. A. Left oblique view of the abdominal aorta showed patency of a large IMA. B. Selective catheterization of the IMA demonstrated wide patency of the vessel, suggesting that the artery would remain patent following stent-graft placement. A decision to perform prophylactic embolization was made. C. A microcatheter was advanced into the IMA and coil embolization was performed. D. Post stent-graft aneurysm repair aortogram showed totally excluded AAA. Note the coils inside

the IMA, projected over the aorta.

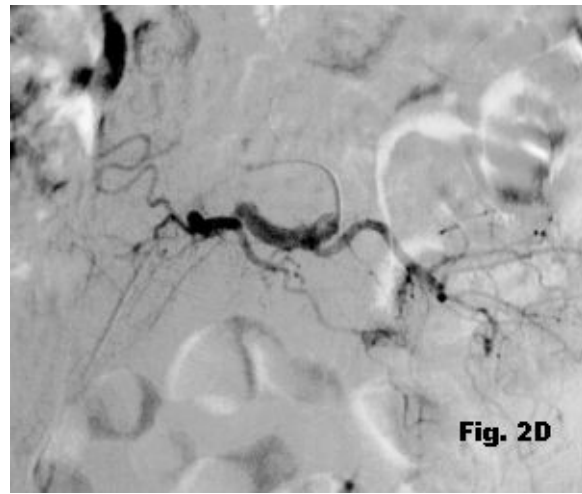
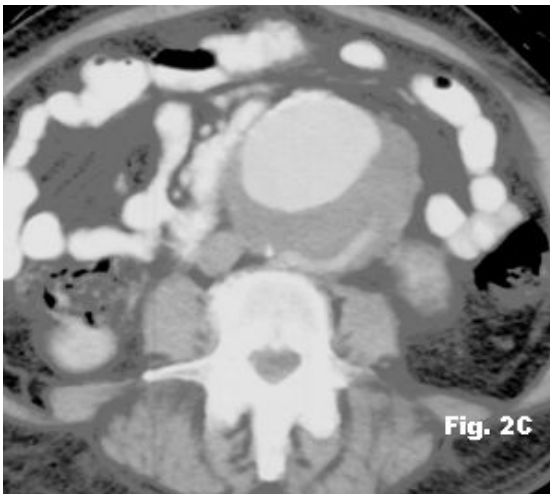
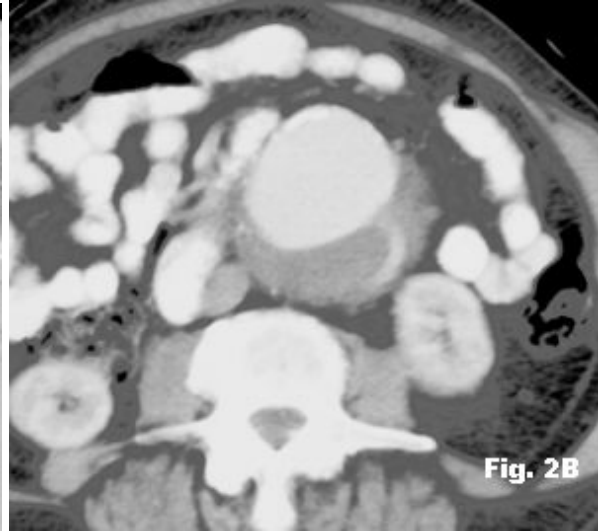
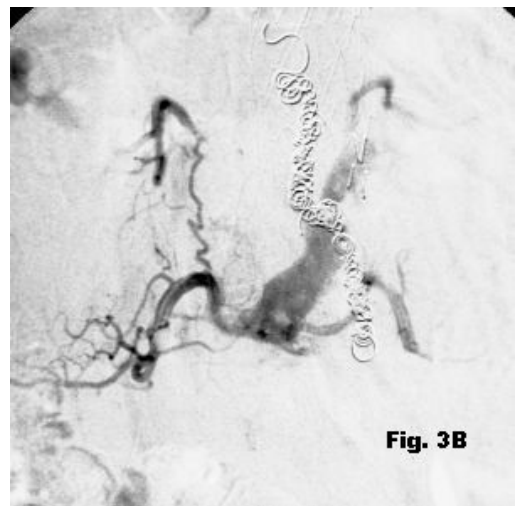
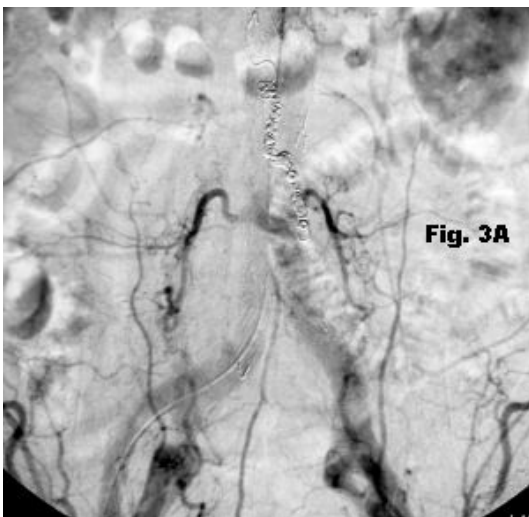




Figure 2. A 81-year-old male patient with AAA presented with significant angulation of the proximal neck and a large aneurysmal sac branch, plus a left lower pole renal artery arising from

the proximal neck. A. Aortogram showed a long but angulated proximal aneurysmal neck. B and C. Axial view of the angio CT of the aorta showed a rather large intra thrombus channel communicating the aneurysm lumen with a lumbar artery. D. Selective injection in the branch showed wide communication with the lumbar arteries. E. A decision was made to perform prophylactic embolization with coils to prevent a type II endoleak. F. Post embolization aortogram showed occlusion of the branch. G. Stent-graft repair of the AAA was successfully performed with total exclusion of the aneurysm. Note the crossed legs and angulation of the left leg, without occlusion. H. Axial view of the one month CT follow up showing exclusion of the aneurysm and the coils occluding the lumbar artery.



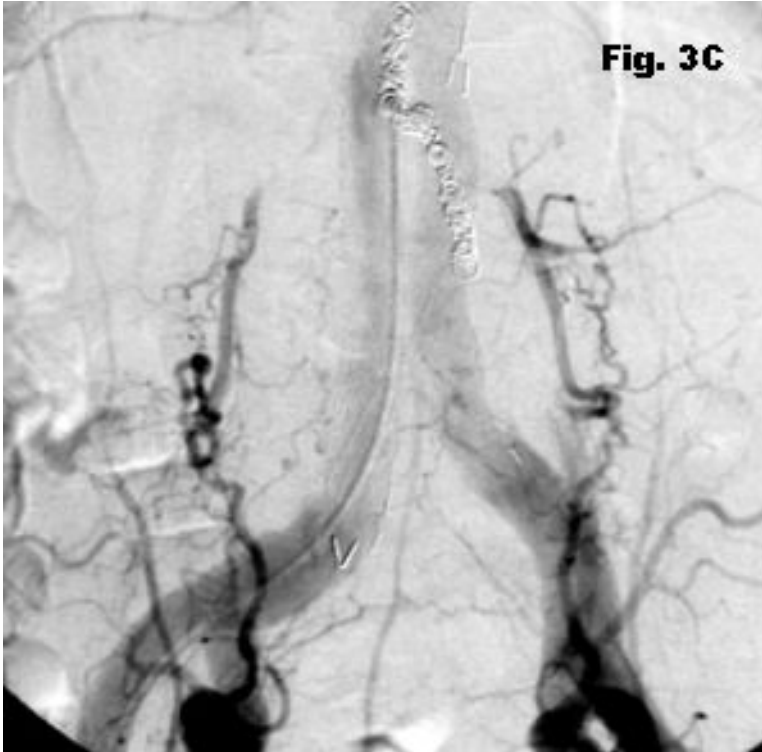


Figure 3. A. Late phase aortogram following stent-graft placement for repair of a large AAA, with a persistent leak from the lumbar arteries. Note type II endoleak projected over the stent-graft. Several coils are visible, used for embolization of the IMA, 1.5 years before. B. Selective injection in the right iliolumbar artery showed significant endoleak. Embolization of both lumbar arteries was performed with Gelfoam pledgets. C. Post embolization aortogram showed

occlusion of both lumbar arteries, with improvement but continued endoleak through the middle sacral artery (not shown). Ultimately the patient was converted to surgery due to increase in aneurysmal sac size.

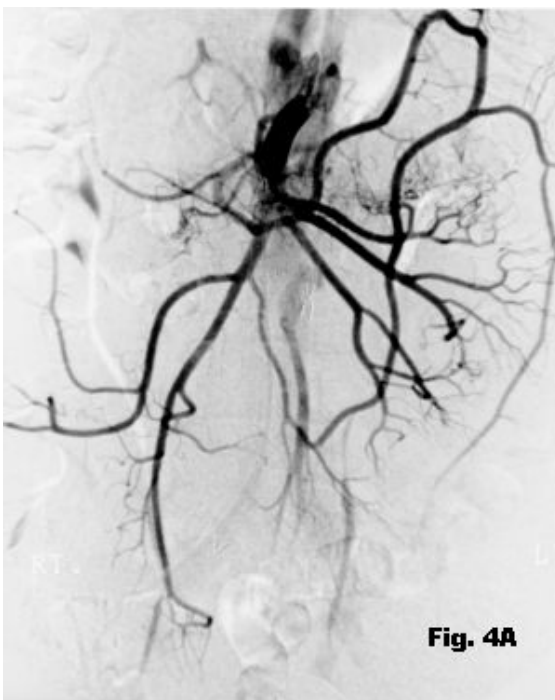


Figure 4. Same patient as in figure 3, approximately 1.5 years apart. A. Selective injection into the SMA showing retrograde flow into the IMA and significant type II endoleak into the aneurysmal sac. B. A selective catheter was used to break the seal in the proximal neck and catheterization of the tract was performed with a microcatheter. Injection of contrast material showed patency of the IMA. E. Embolization with microcoils was performed, including the proximal IMA and the tract inside the aneurysmal sac. (Case provided by John A. Kaufman, M.D.).



**Fig. 4B**



**Fig. 4C**



**Fig. 5A**

Figure 5. 62-year-old male patient with AAA and tortuous iliac arteries. A. Aortogram showed a large aneurysm with a left lower pole renal artery arising from the proximal neck. The lumbar arteries are patent. A small IMA was visible. B. Post stent-graft aneurysm repair aortogram showed adequate exclusion of the aneurysmal sac. C. Discharge angio CT scan and one month angio CT scan showed a large type II endoleak apparently related to a lumbar artery and possibly to the IMA. The tract was tortuous and there was a larger posterior component. D. A translumbar

approach, using CT fluoroscopy guidance was performed with a 18 G needle. The needle was advanced into the aneurysmal sac and into the tract of the endoleak. Injection of contrast material, under CT fluoroscopy, showed flow within the endoleak tract. The volume of the tract was established. E. Two Gelfoam torpedoes mixed with 1,000 IU of Thrombin were used to embolize the lumen of the tract. Note residual contrast within the endoleak tract following embolization. Additional Gelfoam torpedo and Thrombin was used to seal off the hole in the aneurysmal sac wall. Note the radiopaque material outside the aneurysm sac. F. Six months follow up angio CT showed total exclusion of the aneurysm with occlude endoleak and significant reduction in the aneurysm diameter.

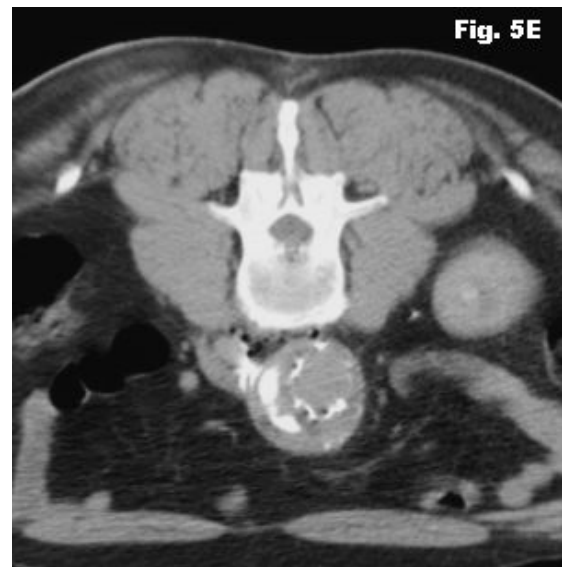




Figure 6. A 68-year-old male with a large type E aneurysm. A. Aortogram showed massive AAA extending from the infrarenal segment to the bifurcation of the common iliac arteries. B. A Talent stent graft was successfully deployed within the AAA. Post procedure aortogram showed a massive type III endoleak from the right limb of the stent-graft, due to laceration of the pre expanded PTFE material (PTFE was used at that time, but is no longer utilized in that device). Embolization with coils was initially performed, but the endoleak reopened within 3 months. C. A 12 mm covered stent was placed within the right limb of the graft at the level of the laceration with total occlusion of the endoleak, as demonstrated in the aortogram. The patient is now 4 years out and the aneurysm has reduced in size, but the pulmonary function is much worse and the patient is on home O2.





Table 1: Types of Endoleaks

Endoleak Type	Description	Probable cause	Relationship to Device	Treatment Alternatives
Type I	Attachment endoleaks (distal or proximal)	Improper graft sizing or vessel measurement Irregularities in the vessel wall	Device related	Cuff placement Embolization Secondary endograft Open repair
Type II	Branch flow endoleaks	Reperfusion via lumbar arteries or IMA. Inadequate identification of feeder vessels and/or graft placement. Use of anticoagulants	Not device related	Conservative Embolization Laparoscopic ligation
Type III	Mid-graft or modular endoleaks	Improper docking of sections. Graft tear or perforations	Device related	Secondary endograft
Type IV	Blushing through the graft fabric	Fabric excessive porosity or prolonged anticoagulation	Device related	Conservative

IMA=Inferior mesenteric artery

Table 2: SVS/ISCVS Medical Risk Factor Categorization

Risk Level	0 (Low)	I (Minimal)	II (Moderate)	III (High)
Age	< 75 yrs	75 - 80 yrs	85 - 90 yrs	> 90 yrs
Cardiac	No CAD	CAD: Mild stable angina or remote MI; Negative coronary angiogram; normal cardiac stress test; LVEF <50% but >30%	CAD: Stable angina or remote MI: mild-to-moderate lesions on coronary angiogram; small reperfusion defects on radionuclide scans; LVEF <30% but >20%	CAD: Unstable angina w/significant areas of myocardium at risk based on coronary angiogram or radionuclide scans; LVEF <20%; recent CHF
Pulmonary	Normal Function	COPD: Able to carry out normal activities or daily life	COPD: Moderate-to-severe pulmonary dysfunction	COPD: Requiring home O2; FEF 25-75 <20% of predicted
Renal	Normal Function	Mild renal dysfunction; Creatinine <2mg/dL	Renal dysfunction; Creatinine 2-3.5 mg/dL	Chronic dialysis; Creatinine > 3.5 mg/dL
Predicted Mortality Rate	0 - 1 %	1 - 3%	3 - 8 %	8 - 30 %

From: Zarins CK, Harris EJ. J Endovascular Surg 1997;4:232-241

SVS=Society of Vascular Surgery; ISCVS=International Society for Cardiovascular Surgery; CAD = Coronary Artery Disease; COPD = Chronic Obstructive Pulmonary Disease; MI = Myocardial Infarction; LVEF = Left Ventricular Ejection Fraction; CHF = Congestive heart failure

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