# AAA;Surgery is absolutely better

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# Transfemoral Intraluminal Graft Implantation for Abdominal Aortic Aneurysms

*J.C. Parodi, MD,* J.C. Palmaz, MD,† and H.D. Barone, PhD, Buenos Aires, Argentina, and San Antonio, Texas*

This study reports on animal experimentation and initial clinical trials exploring the feasibility of exclusion of an abdominal aortic aneurysm by placement of an intraluminal, stent-anchored, Dacron prosthetic graft using retrograde cannulation of the common femoral artery under local or regional anesthesia. Experiments showed that when a balloon-expandable stent was sutured to the partially overlapping ends of a tubular, knitted Dacron graft, friction seals were created which fixed the ends of the graft to the vessel wall. This excludes the aneurysm from circulation and allows normal flow through the graft lumen. Initial treatment in five patients with serious co-morbidities is described. Each patient had an individually tailored balloon diameter and diameter and length of their Dacron graft. Standard stents were used and the diameter of the stent-graft was determined by sonography, computed tomography, and arteriography. In three of them a cephalic stent was used without a distal stent. In two other patients both ends of the Dacron tubular stent were attached to stents using a one-third stent overlap. In these latter two, once the proximal neck of the aneurysm was reached, the sheath was withdrawn and the cephalic balloon inflated with a saline/contrast solution. The catheter was gently removed caudally towards the arterial entry site in the groin to keep tension on the graft, and the second balloon inflated so as to deploy the second stent. Four of the five patients had heparin reversal at the end of the procedure. We are encouraged by this early experience, but believe that further developments and more clinical trials are needed before this technique becomes widely used (*Ann Vasc Surg* 1991;5:491–499).

**KEY WORDS:** Graft-stent exclusions; grafts; abdominal aortic aneurysm; transfemoral intraluminal grafts.

# Surgery for AAA

- Surgical repair of the asymptomatic AAA causes substantial morbidity and is considered the exemplar of high-risk elective surgery.
  ; Medical co-morbidities
  Technical factors

- Study for small (< 5.5 cm) AAA,  NEJM, 2002
  ; Survival is not improved by elective repair, even when operative mortality is low.

# EVAR for AAA

- AAA exclusion from the circulation can prevent aneurysm rupture.

  ; Theoretically, occlusion of the lumbar arteries and mesenteric artery could be expected to follow intraluminal graft replacement by atheromatous aneurysmal wall or intraluminal thrombus.

- Lack of aortic cross clamping allows graft exclusion of the aneurysm without cardiac compromise.

The Royal College of Surgeons of England

Ann R Coll Surg England 1999; **81**: 161–165

# The highs and lows of endovascular aneurysm repair: the first two years of the Eurostar Registry

Peter L. Harris

*Regional Vascular Unit, Royal Liverpool University Hospital, Liverpool, UK*

**The Eurostar Registry was established in 1996 to collate information, from centres across Europe, on the outcome from endovascular grafting of aortic aneurysms. At the end of the first year of the project, data on 430 patients had been entered onto the database. In 420 patients (97.7%), the endografts were deployed without major complications. The 30-day mortality rate was low at 3.4% and deaths were confined mostly to 'high risk' patients with major co-morbidity. Endoleaks, which were present on discharge from hospital in 15.7% of patients, were associated with a significantly increased incidence of continued expansion of the aneurysm sac postoperatively ($P < 0.01$). Thus the early results confirmed the feasibility and low complication rate of endovascular repair of aneurysms, but a higher than expected incidence of endoleaks.**

**At 2 years, 895 patients had been registered. The rate of early endoleaks remained significantly unchanged but another 18% of patients had developed new endoleaks during the first year of follow-up. Six delayed ruptures had been reported, 3 fatal. There were indications that 'self sealed' endoleaks continued to pressurise the aneurysm sac. Severe distortion of the grafts with kinking and other structural changes associated with postoperative longitudinal shrinking of the aneurysm sac was observed in 69% of patients at 1 year. Clinical complications associated with these changes included late endoleak and graft limb occlusion.**

**Early unrealistic optimism about endovascular aneurysm repair has been replaced with a more realistic understanding of its benefits and limitations as a result of the Eurostar project and other registries. Randomised studies are now required to establish the most appropriate role for this approach, alongside established therapies.**

*All new therapies work miraculously . . . for a while!*

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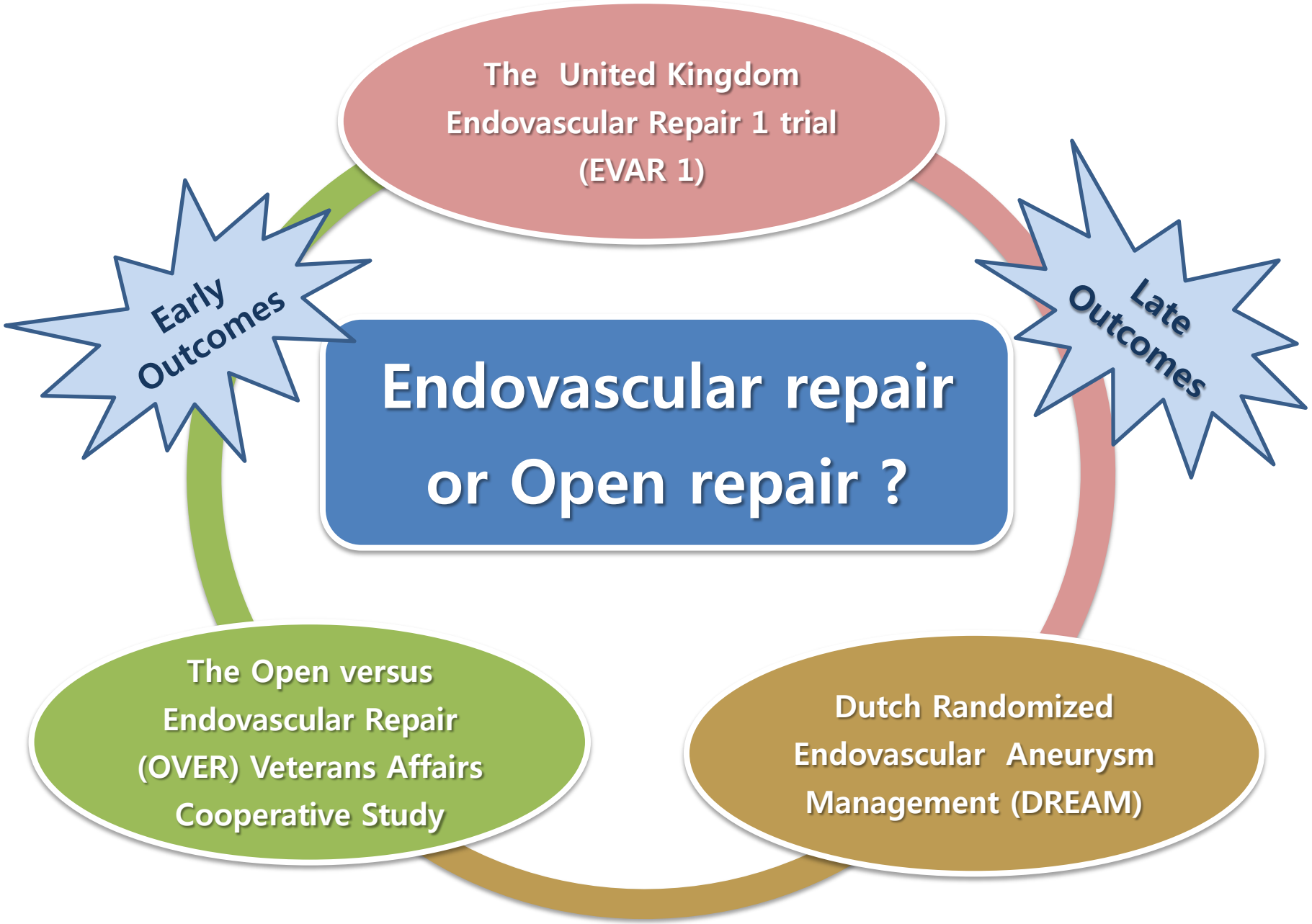

The United Kingdom Endovascular Repair 1 trial (EVAR 1)
Early Outcomes
Late Outcomes
Endovascular repair or Open repair ?
The Open versus Endovascular Repair (OVER) Veterans Affairs Cooperative Study
Dutch Randomized Endovascular Aneurysm Management (DREAM)

## Dutch Randomized Endovascular Aneurysm Management (DREAM)

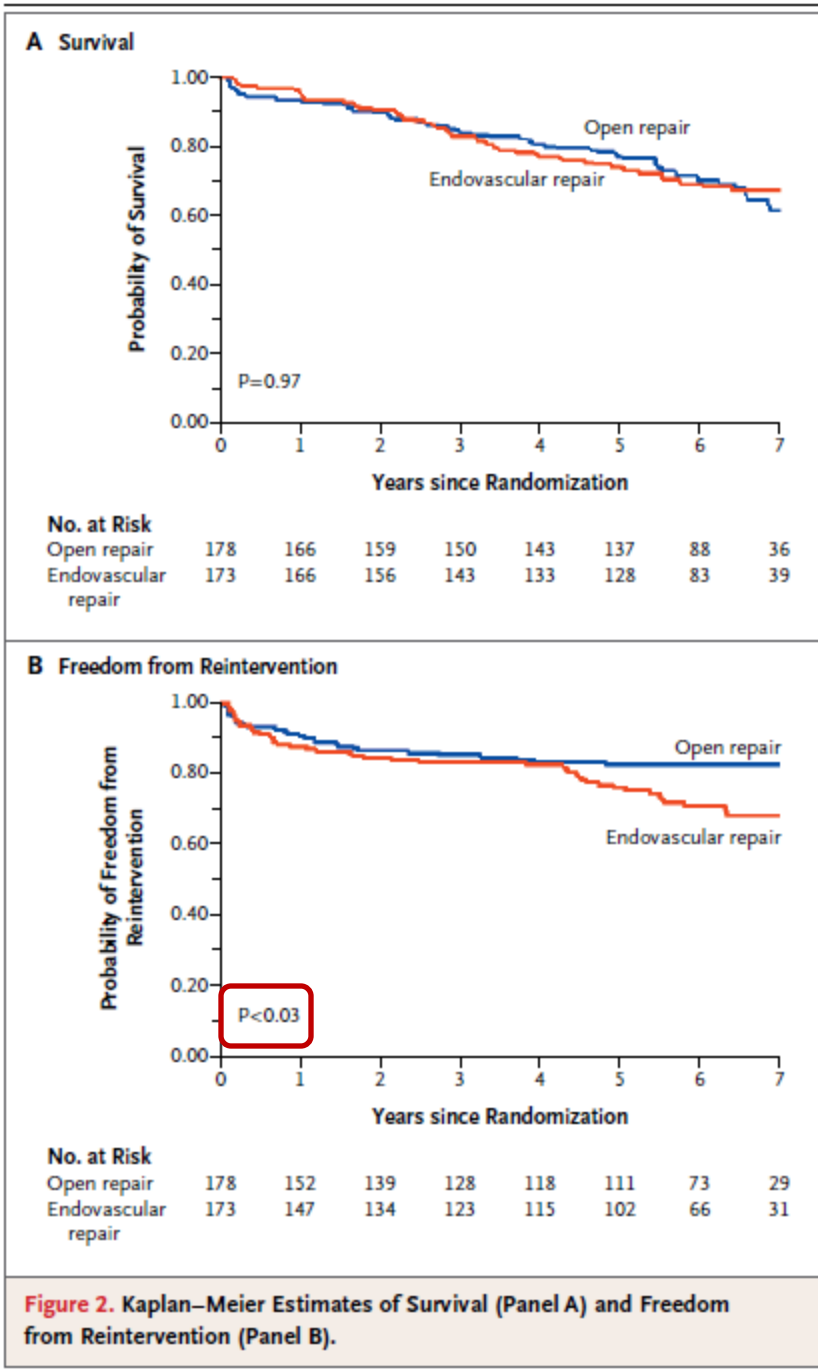



Figure 2. Kaplan–Meier Estimates of Survival (Panel A) and Freedom from Reintervention (Panel B).

**Cummulative overall survival rates**

- Open : 69.9%
- Endovascular : 68.9%

A difference of 1.0 percentage point (95% CI, -8.8 to 10.8; p=0.97)

**Cummulative rates of freedom from secondary interventions**

- Open : 81.9%
- Endovascular : 70.4%

A difference of 11.5 percentage point (95% CI, 2.0 to 21.0; p=0.03)

## The United Kingdom Endovascular Repair 1 trial (EVAR 1)

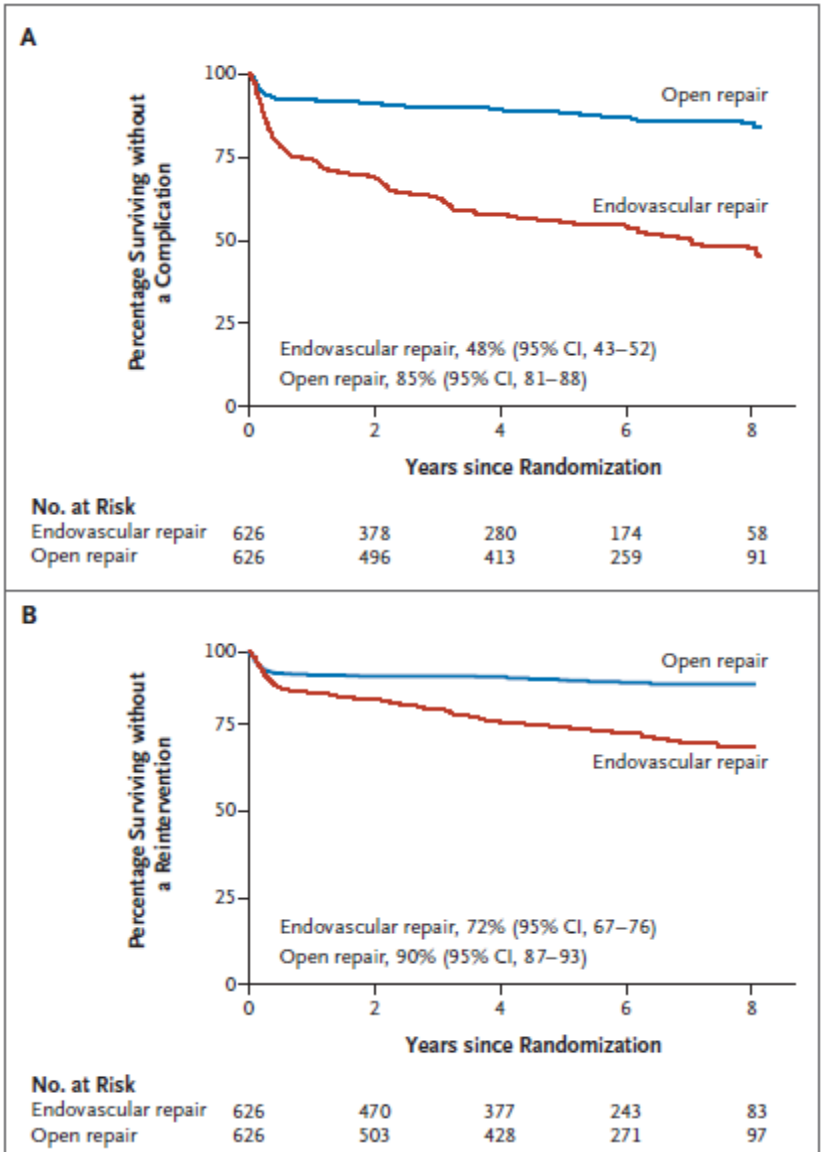



**Figure 2. Kaplan–Meier Estimates for the Time to the First Graft-Related Complication or Reintervention during 8 Years of Follow-up.**

The rates of graft-related complications (Panel A) and reinterventions (Panel B) were higher among patients in the endovascular-repair group than among those in the open-repair group. New complications occurred throughout the 8-year follow-up period, contributing to the higher overall costs of the endovascular procedure.

Endovascular repair was associated with increased rates of complications and reinterventions and was more costly. *(p=0.01, p=0.001)*

# Early outcomes vs. Late outcomes

**The Open versus Endovascular Repair (OVER) Veterans Affairs Cooperative Study**

**Endovascular : 61**

- Endovascular : 42
- Conversion to open : 3
- Other arterial procedure : 9
- Wound : 5
- Amputation : 2

**Open : 55**

- Incisional hernia :24
- Endovascular :7
- Wound complications : 4
- Amputations : 4
- Laparotomy for bowel obstruction : 4
- Laparotomy for hematoma: 2
- Relieve claudication : 8
- Miscellulaneous : 8

| | | | |
|---|---|---|---|
| Unknown | 1 (0.2) | 4 (0.9) | .21 |
| Patients with procedure failure | 58 (13.1) | 51 (11.7) | .53 |
| Patients with no repair attempted | 4 (0.9) | 5 (1.1) | .75 |
| Patients with aborted initial procedure | 8 (1.8) | 6 (1.4) | .61 |
| Patients having secondary therapeutic procedures | 46 (10.4) | 40 (9.2) | .73 |
| All secondary therapeutic procedures, No. of events | 61 | 55 | |
| Patients with any 1-year major morbidity | 18 (4.1) | 20 (4.6) | .70 |
| Myocardial infarction | 6 (1.4) | 12 (2.7) | .14 |
| Stroke | 7 (1.6) | 4 (0.9) | .38 |
| Amputation | 1 (0.2) | 3 (0.7) | .37 |
| Renal failure requiring dialysis | 5 (1.1) | 3 (0.7) | .73 |
| Patients with new or worsened claudication | 37 (8.3) | 20 (4.6) | .02 |
| All postrepair aneurysm-related hospitalizations, No. of events | 108 | 86 | |

Abbreviation: AAA, abdominal aortic aneurysm.
[a] Includes all deaths within 30 days after repair or during hospitalization.
[b] Includes cerebrovascular disease, injury, pneumonia, other infections, and unexplained sudden deaths not considered AAA-related.

**Endovascular : 148**

- Endovascular : 100
- Conversion to open : 9
- Other arterial procedure : 19
- Wound : 11
- Amputation : 6
- Miscellulaneous : 4

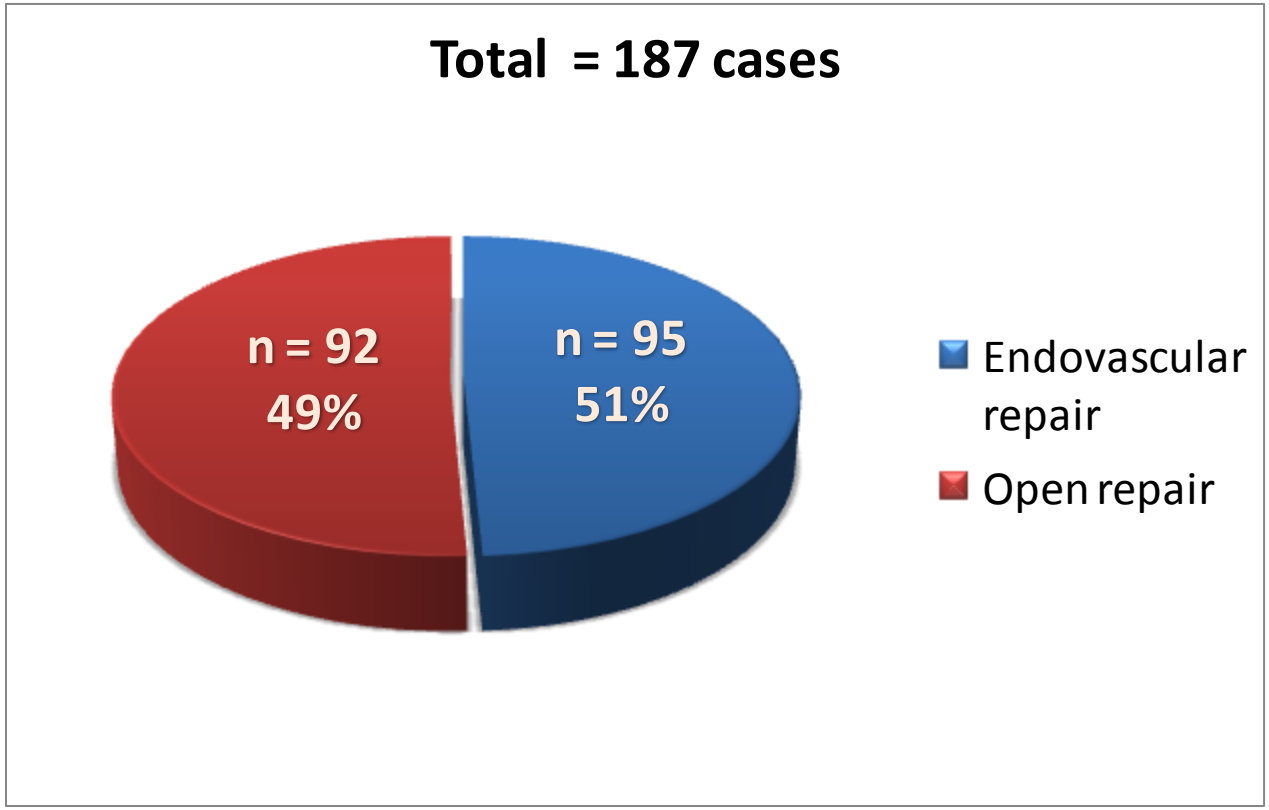
**Open : 105**

- Incisional hernia : 48
- Endovascular : 15
- Wound complications : 4
- Amputations : 7
- Laparotomy for bowel obstruction : 11
- Open arterial procedure : 13
- Miscellulaneous : 7

| | | | |
|---|---|---|---|
| Other cause | 15 (3.4) | 9 (2.1) | 0.23 |
| Unknown cause | 13 (2.9) | 15 (3.4) | 0.67 |
| Aneurysm rupture | 6 (1.4) | 0 | 0.03 |
| New or worsened claudication — no. of patients (%) | 23 (5.2) | 15 (3.4) | 0.20 |
| Secondary therapeutic procedures | | | |
| No. of patients (%) | 98 (22.1) | 78 (17.8) | 0.12 |
| No. of procedures | 148 | 105 | 0.26 |
| Hospitalizations after repair | | | |
| Total no. of hospitalizations | 954 | 1040 | 0.08 |
| Total no. of patients with one or more hospitalizations (%) | 325 (73.2) | 314 (71.9) | 0.66 |
| Hospitalizations related to aneurysm | | | |
| No. of hospitalizations | 171 | 117 | 0.12 |
| No. of patients (%) | 95 (21.4) | 78 (17.8) | 0.19 |

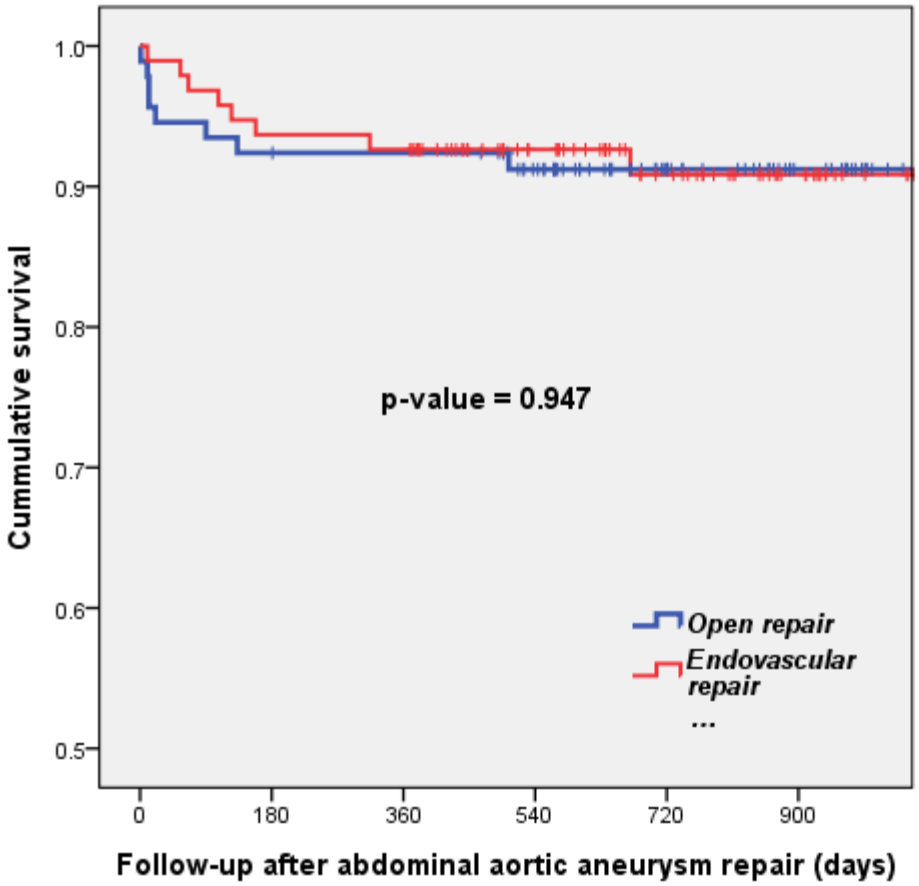
# AMC (2009.07-2011.12)

- Abdominal aortic aneurysm



# Complications and Secondary procedures

| | Open repair | Endovascular repair | |
|---|---|---|---|
| **Complication after procedure** | 15/92 (16.3) | 34/95 (35.8) | 0.002 |
| **Colonic ischemia** | 7/15 (46.7) | 2/34 (5.9) | |
| **Lower extremity ischemia** | 2/15 (13.3) | | |
| **Ileus, bowel obstruction** | 5/15 (33.3) | | |
| **Incisional hernia** | 1/15 (6.7) | | |
| **Endoleak** | | 25/34 (73.5) | |
| **Graft limb occlusion** | | 4/34 (11.8) | |
| | | 1/34 (2.9) | |
| **Stent graft infection** | | 2/34 (5.8) | |
| **Secondary therapeutic procedure** | 5/92 (5.4) | 11/95(11.6) | 0.020 |
| **Arterial surgery** | 1/5 (20.0) | | |
| **Laparotomy for bowel complication** | 4/5 (80.0) | | |
| **Embolization due to endoleak** | | 5/11 (45.5) | |
| **Stent insertion due to endoleak** | | 2/11 (18.2) | |
| **Stent insertion due to graft limb occlusion** | | 2/11 (18.2) | |
| **Stent insertion** | | 1/11 (9.0) | |
| **Thrombectomy** | | 1/11 (9.0) | |

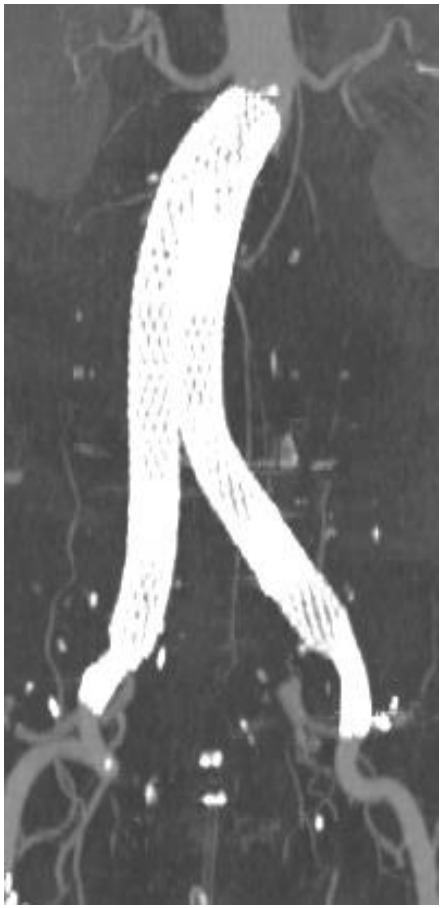


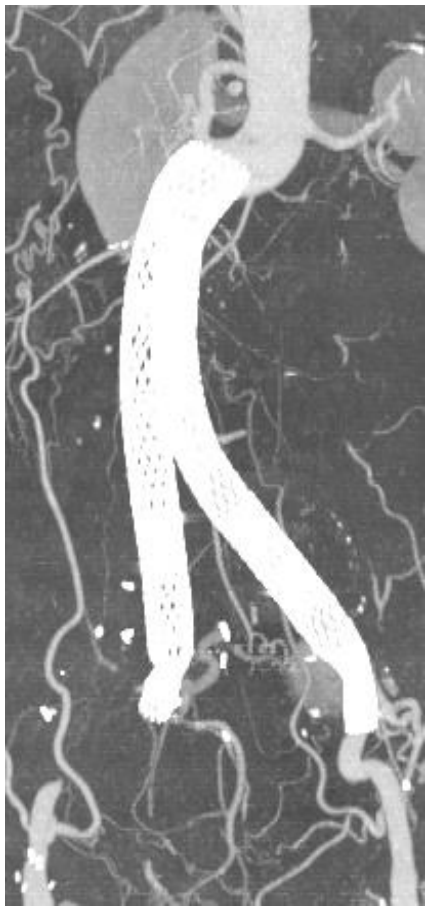

Kaplan-Meier estimates of survival during & years of follow-up.

- There were no significant difference in survival.

M/ 72, asymptomatic
72 mm AAA

POD 17 months



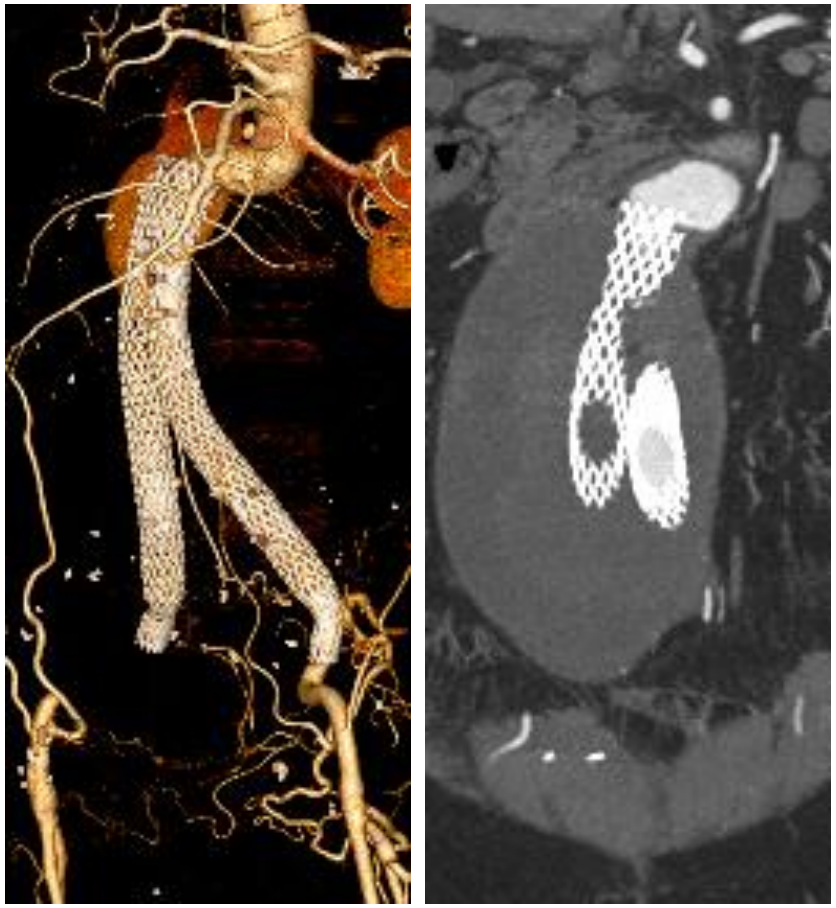


2008-8-7

2010-3-17

72 -> 78 mm

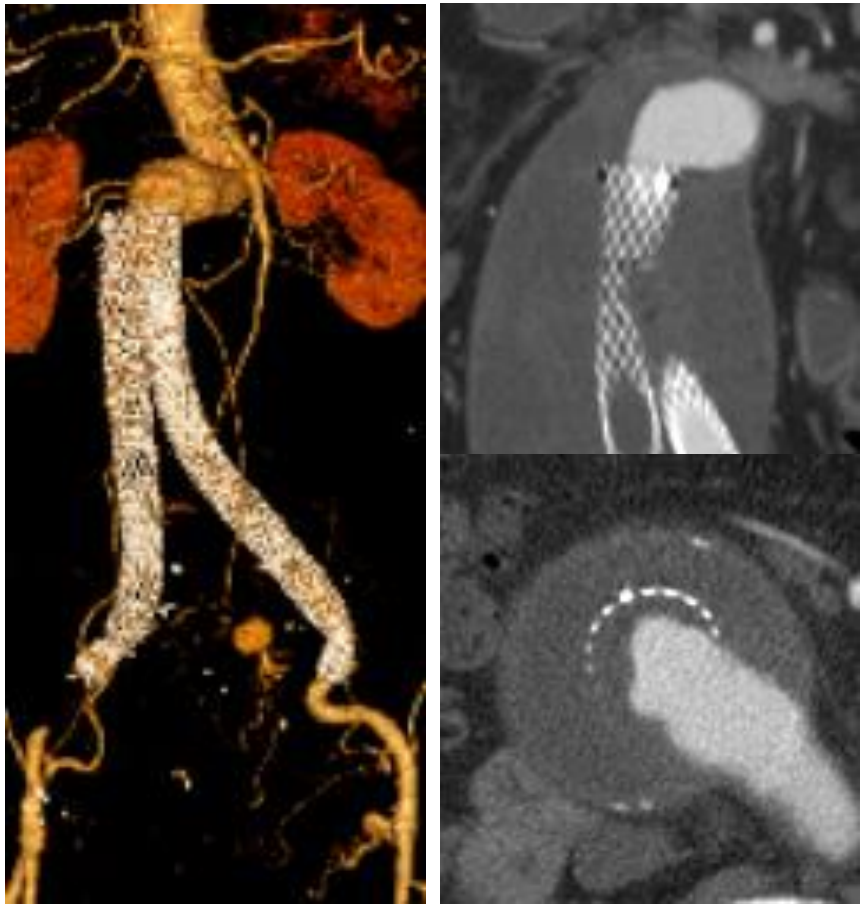
POD 33 months



2011-9-27

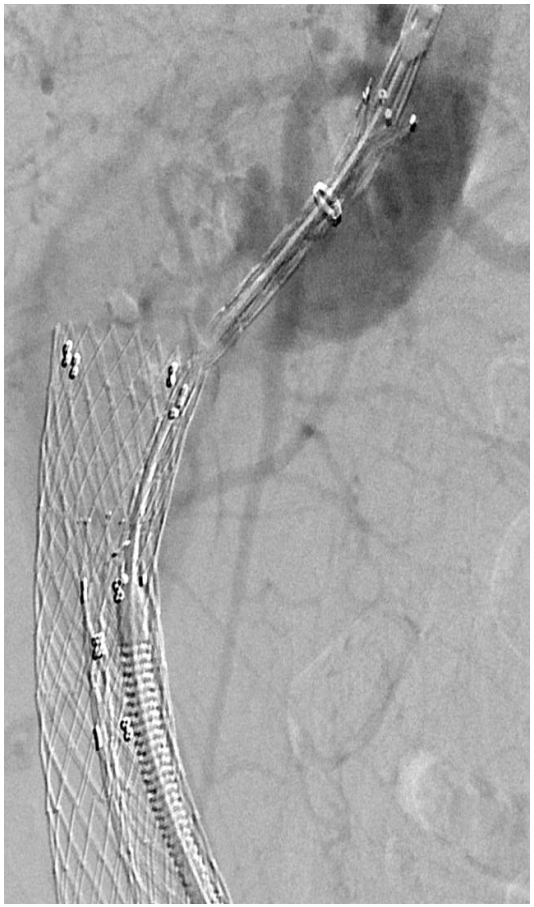
78 -> 82 mm

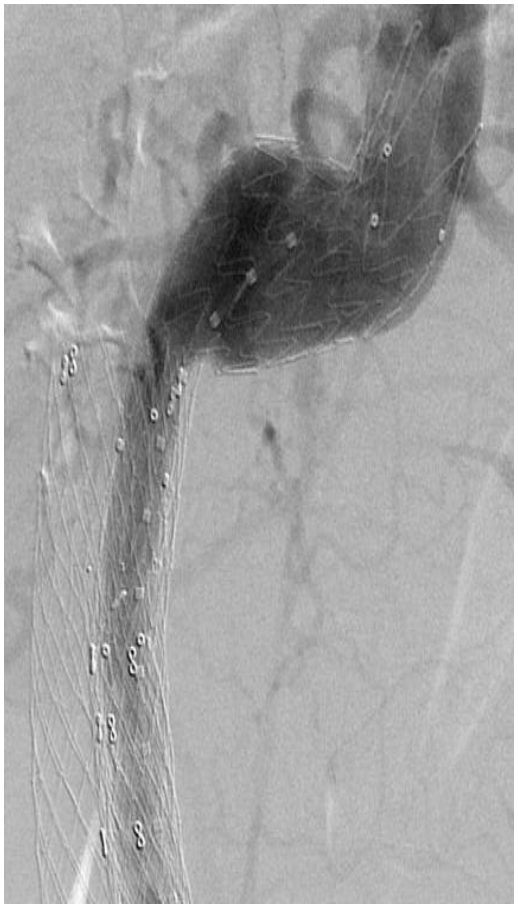
POD 47 months



2012-11-6

82 -> 88 mm, symptomatic



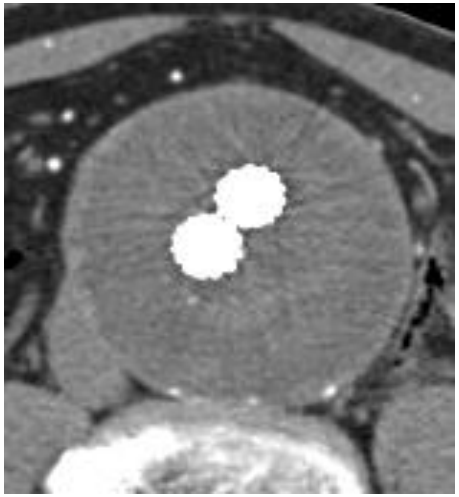


2012-11-7

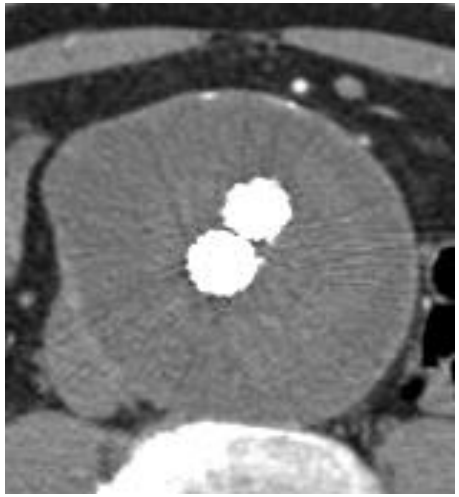
2013-2-18

88 -> 88 mm

M/64,
asymptomatic
68 mm AAA,

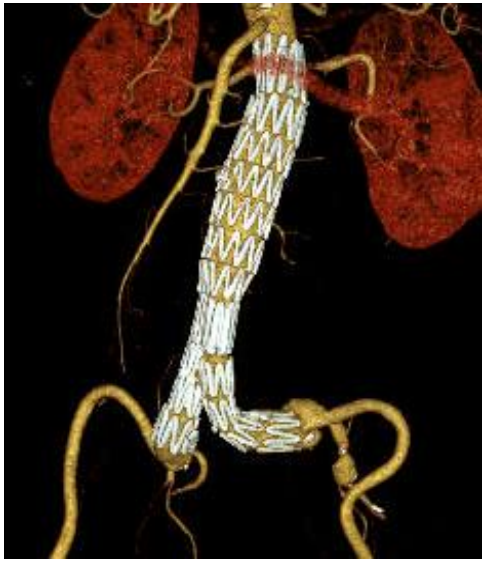


2011-8-11



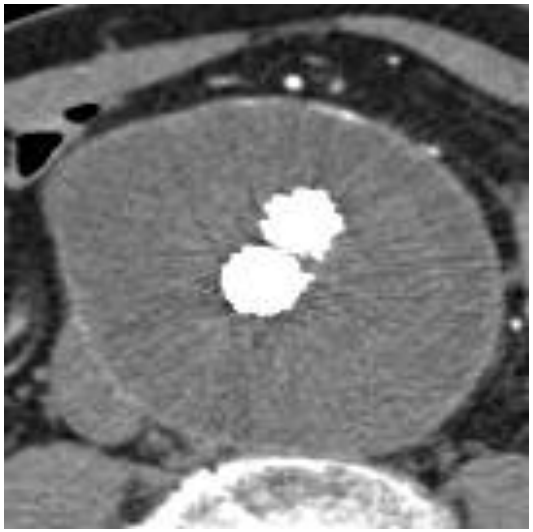
2011-11-9

68 -> 75 mm

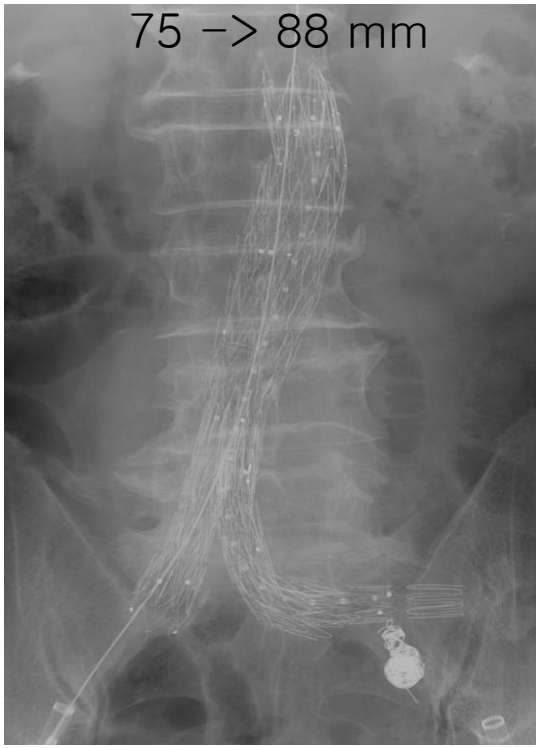


2011-11-22

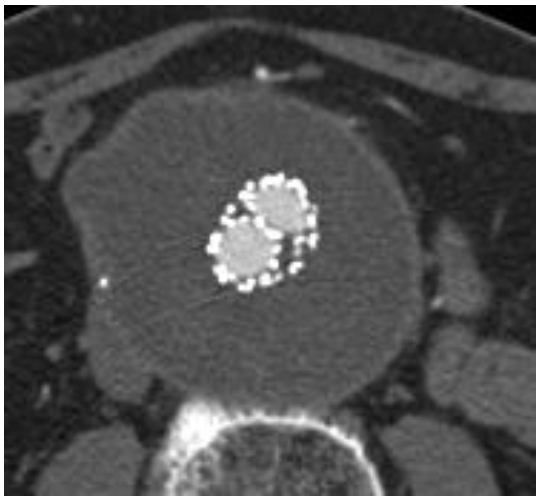
POD 3 months



75 -> 88 mm

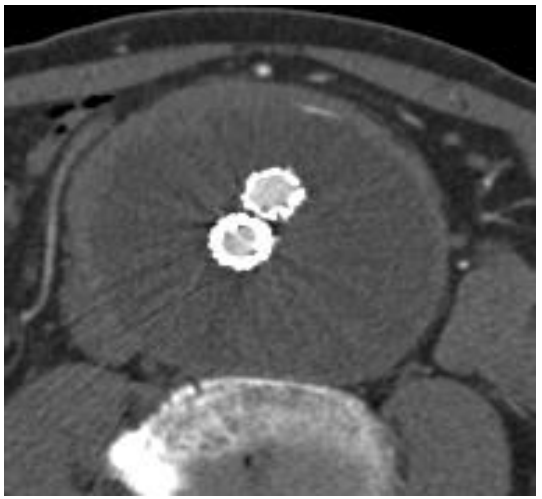


2012-1-12 (POD 5 months)



88 -> 84 mm

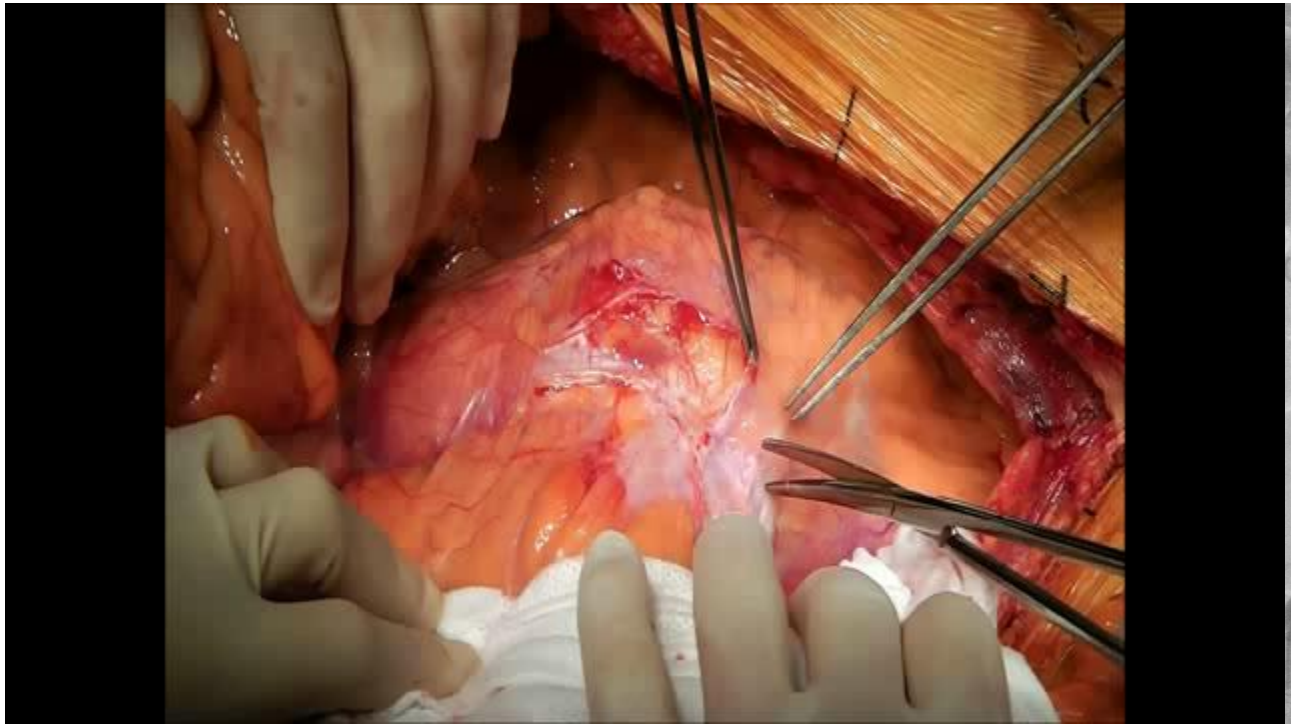
2012-3-6



84 -> 95 mm

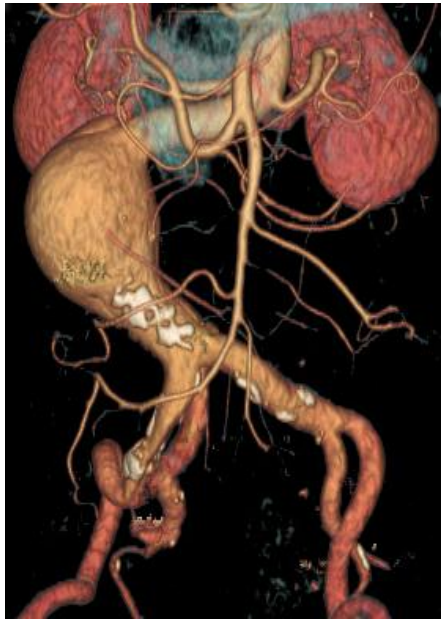
2012-12-5

POD 16 months

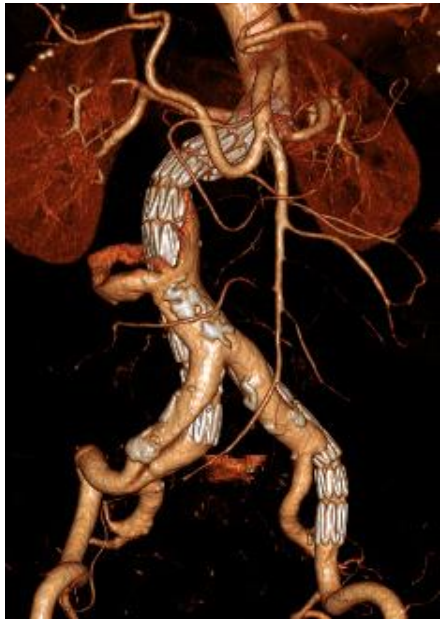


2013-2-5

F/ 70, symptomatic
57 mm AAA,

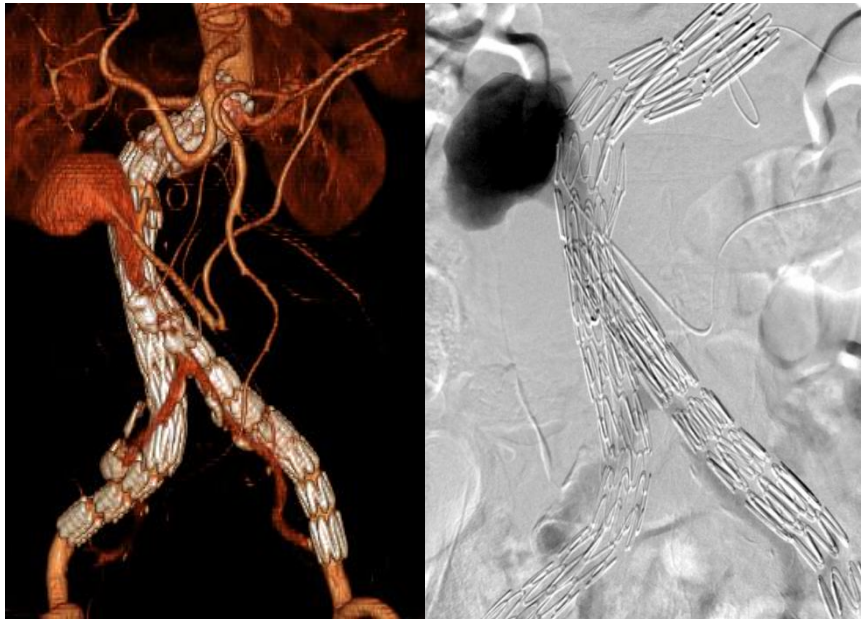


2012-3-20
EVAR



2012-4-3

Bilateral IIA embolization and limb extension

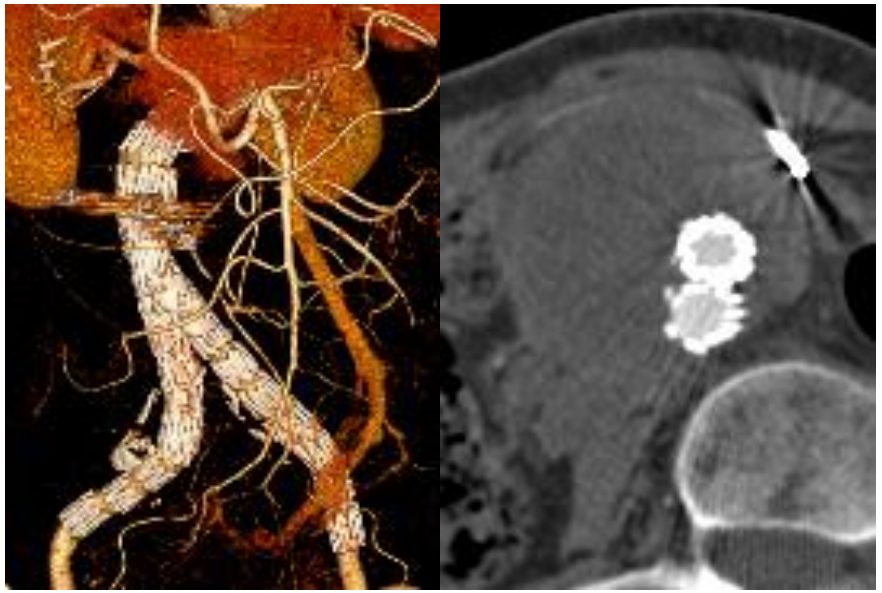


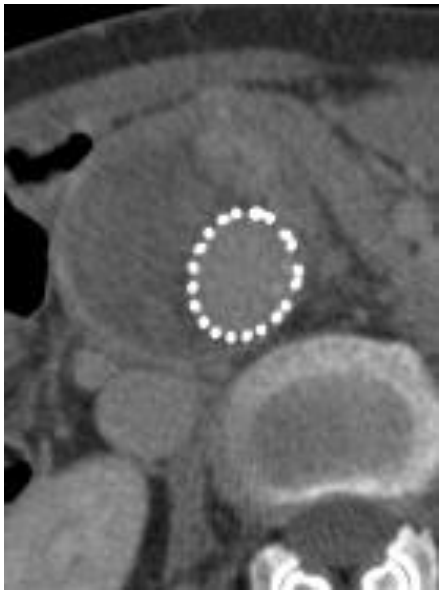
2012-6-28 (POD 3 months)

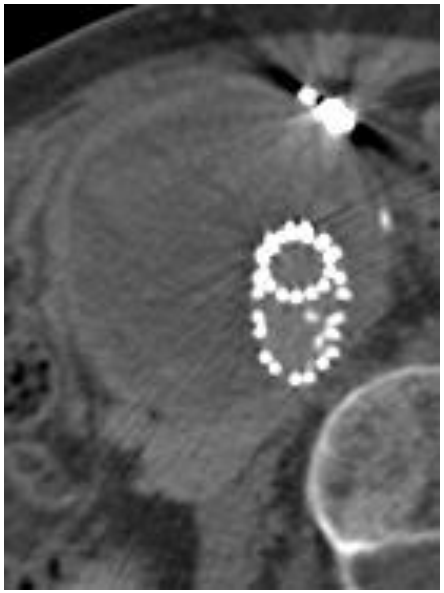
IMA embolization

POD 10 months

POD 13 months







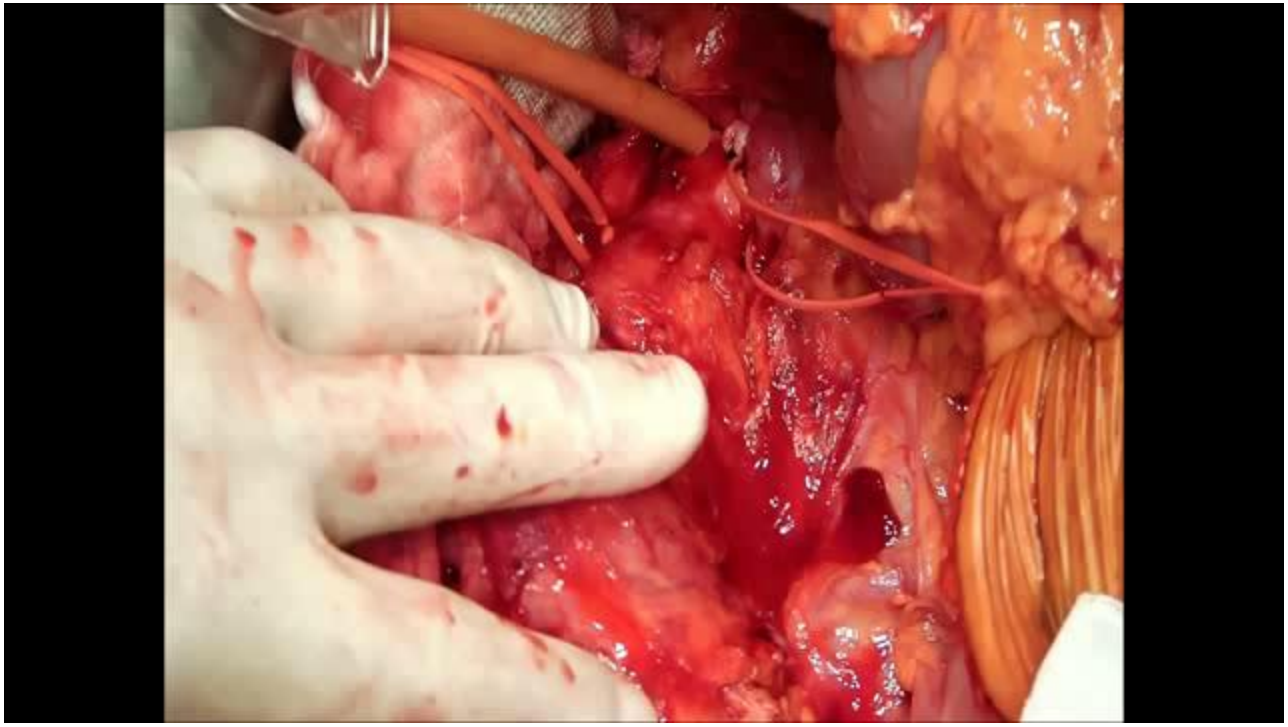
2012-7-28

2013-1-24

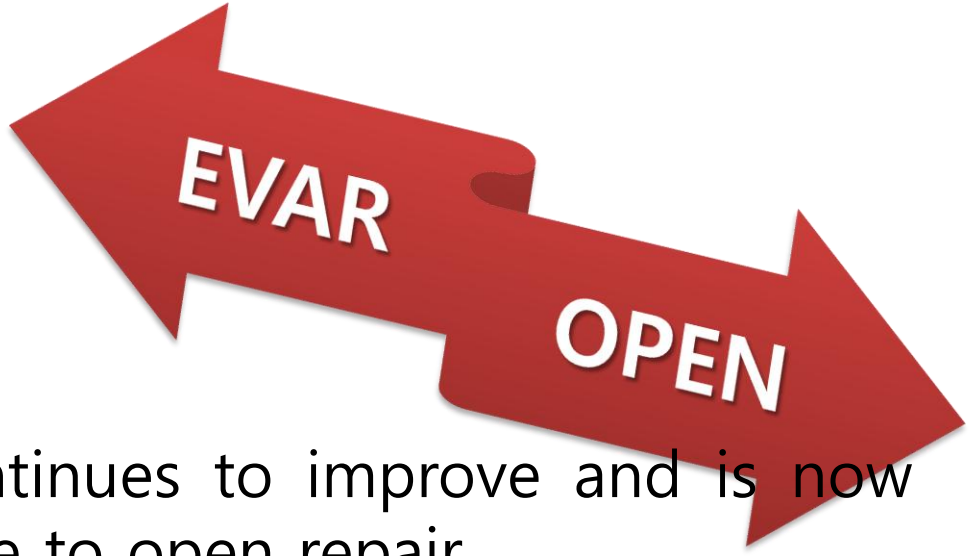
57 -> 57 mm

2013-4-17

57 -> 62 mm



# Summary




- ✓ Endovascular repair continues to improve and is now an acceptable alternative to open repair.
- ✓ The endovascular can be associated with a significantly lower operative mortality in early periods.
- ✓ No significant differences were seen in overall in the long-term.
- ✓ Endovascular repair has tendency to increase the rates of complications and reinterventions.

# Conclusion