Periprosthetic leak and rupture after endovascular repair of abdominal aortic aneurysm: The significance of device design for long-term results

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We present a case of abdominal aortic aneurysm treated with an endovascular bifurcated aortic graft in which a periprosthetic leak caused by a tear in the polyester prosthesis appeared between 9 and 12 months after surgery. The tear appeared adjacent to a suture breakage that caused separation of two struts of the nitinol wire framework in the body of the stent graft. The leak was sealed with insertion of a new endovascular tube graft into the body of the bifurcation. Eight months later, the patient had a nonfatal rupture of the abdominal aortic aneurysm because detachment of the second limb from the bifurcation caused a new major periprosthetic leak. According to the manufacturer of this device, suture breakage with separation of metal components is commonly seen, but perforation of the polyester prosthesis caused by movement of the metal stent against the fabric has not been reported. It is likely that this occurred in our patient. Detachment of the second limb from the bifurcated stent, causing a rupture, has been described before. Increasing angulation and tortuosity of the stent graft, as a result of either remodeling of the sac or elongation of the stent, and reduced compliance to angulation after the stent-in-stent procedure might have contributed to the detachment in this case. (J Vasc Surg 1999;29:1152-8.)

Endovascular repair of abdominal aortic aneurysms has been shown to be feasible with short-term results comparable with conventional surgical repair in carefully selected patients.[1,2] Long-term results are not known, and especially worrisome is the problem of periprosthetic leak because persistent or secondary leak might mean a persistent rupture risk.[3-5] Causes of periprosthetic leak are insufficient seal of the proximal or distal stents of the device or backflow from aortic branches. It also may be caused by leak from the stent graft itself, either in the connection of different components of the stent system or through tears in the prosthetic cover. With further analysis, the reasons for these problems could be improper selection of patients and devices, technical problems during insertion, or migration and kinking because of remodeling of the vessels in the long term. Many different devices with different designs are available, and little is known regarding comparison of their performance.

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CASE REPORT

An 80-year-old man was seen with an asymptomatic 70-mm abdominal aortic aneurysm. Medically and technically, he was found suitable for endovascular repair (Fig 1*A*). Informed consent was obtained, and treatment was performed in September 1996. A Vanguard bifurcated endovascular aortic graft (Boston Scientific Corporation, Paris, France) was placed without complications. The completion angiographic results showed no leak (Fig 1*B*), and neither could any derangement of the stents be seen on plain films without contrast.

Helical computed tomography (CT) angiography and color Doppler scanning (CDS) were performed on day 2 and after 1, 3, 6, 9, and 12 months. At all follow-up visits until 9 months, a small contrast filling was seen in the

aneurysm sac, posteriorly and 2 cm caudal to the bifurcation behind the stent limbs. We suspected backflow from lumbar arteries but could not find any significant arteries on CT and CDS results. The contrast filling was unchanged through this time, and the aneurysm diameter was stable at 70 mm (Fig 2*A*). The location of the stent in the aneurysm sac, however, was changing by taking a more tortuous course through the sac. This could have been caused by a remodeling (shortening) of the sac, even if the diameter was not reduced. Another explanation might have been elongation of the stent itself. The position of the stent in the infrarenal neck and in the common iliac arteries was not changing. Plain x-rays showed no signs of suture breakage or derangement of metal parts nor any sign of reduced overlap between the second limb and the bifurcation part.

To investigate possibilities of coil embolization of lumbar arteries, selective angiography of the internal iliac arteries was performed after 9 months. A plexus of ileolumbar arteries connected to branches of the right internal iliac artery and to the aneurysm sac was shown but was considered too small for embolization. Further observation was decided.

At 12 months (September 1997), the CT scanning results showed a considerably increased leak and an increase in aneurysm diameter in the last 3 months from 70 to 80 mm (Fig 2*B*). The patient had no symptoms but was admitted immediately. CDS results showed a 9 mm–thick jet flow out of the body of the stent graft posteriorly into the aneurysm sac. The lesion of the graft was located 15 mm proximal to the bifurcation. The finding was confirmed with angiography (Fig 3*A,B*), which also revealed large right and left lumbar arteries and the middle sacral artery serving as outflow for the leak. A video film without contrast showed a suture breakage adjacent to the graft lesion, which resulted in separation and increased mobility of metal parts, the two adjacent struts moving independently into the covering polyester prosthesis with the heart beats. The stent was angulated, and the suture breakage and graft tear were on the outer curvature and posterior. The overlap between the second limb and the bifurcation was not changed.

An attempt of endovascular repair was decided, and an endovascular tube graft (Vanguard straight endovascular aortic graft) was inserted into the body of the formerly placed bifurcated stent graft (Fig 3*C*). The diameter was 22 mm, which was the same as the diameter of the bifurcation stent. During insertion, the metal struts of the bifurcated stent could be seen to be further deranged. When the tube stent graft was placed and dilated, the leak was sealed except for a minimal stripe of contrast. The flow direction in the lumbar arteries was immediately reversed because they were now filled from the internal iliac arteries. The position of the metal markers in the junction between the bifurcation and the second limb was not changed during the insertion of the tube stent graft.

On CT scan 1 month after tube stent graft placement, the lumbar arteries still filled contrast into the aneurysm sac and they now had a caliber that could be accessed with an embolization catheter. Coil embolization was performed in November 1997, with access from the right internal iliac artery through a right lumbar artery into the aneurysm sac. The mean pressure in the aneurysm sac measured before embolization was 100 mm Hg and was equal to the pressure in the external iliac artery. From this position, coils were placed into the left lumbar artery and the middle sacral artery, and when the catheter was withdrawn, coils were also placed in the right lumbar artery. Completion angiographic results showed no endoleak. CDS results the following day showed a minor blood flow from the right lumbar artery into the aneurysm sac.

Three months later (January 1998), CT angiographic

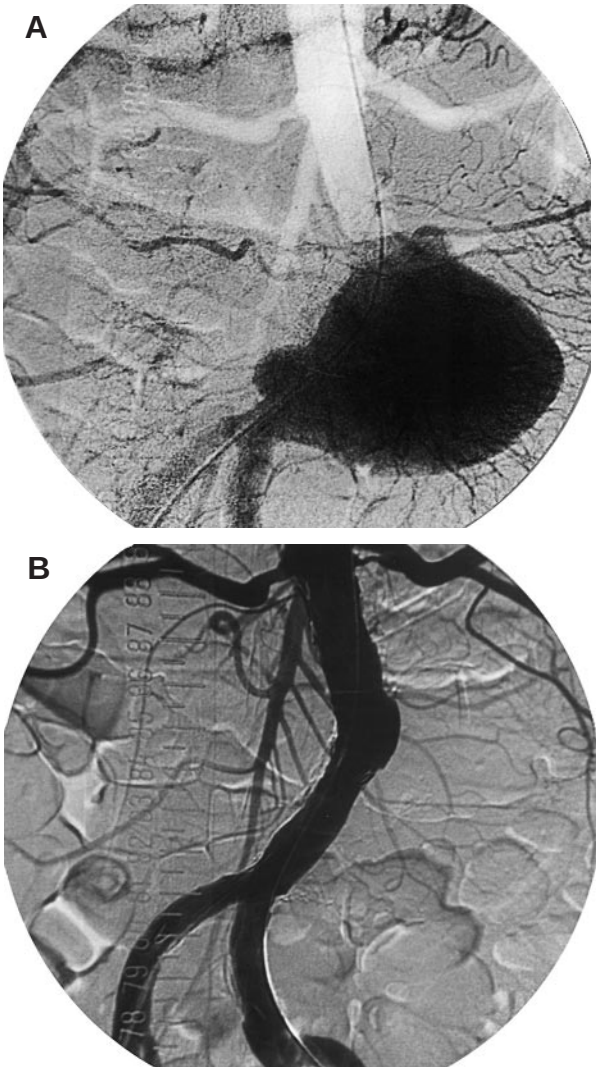

Fig 1. Preoperative angiogram **(A)** and completion angiogram **(B)** after primary treatment with Vanguard bifurcated endovascular aortic graft (Boston Scientific Corporation, Paris, France). Note proximal V-shaped marker of stent graft close to right renal artery.

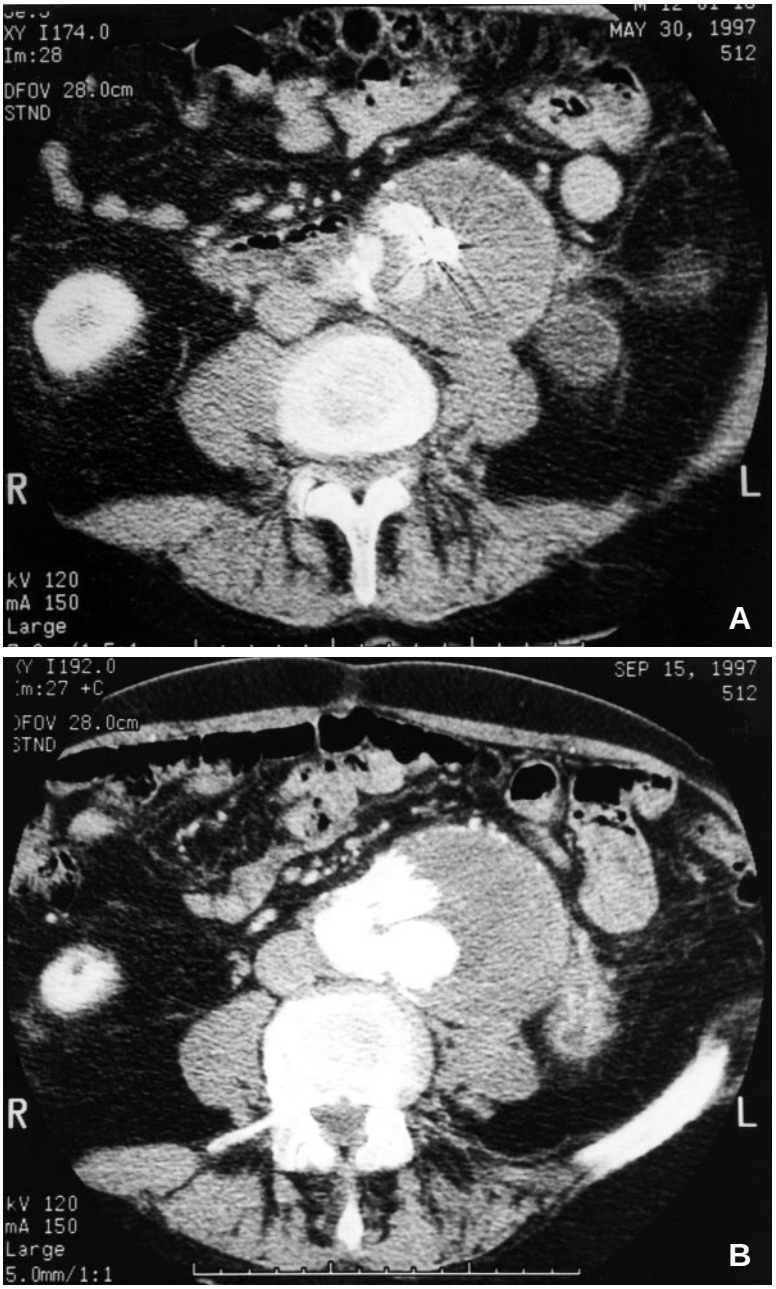

Fig 2. Computed tomographic scans at **(A)** 9 months and **(B)** 12 months showing increased periprosthetic leak from tear in prosthesis and increased aneurysm diameter.

results showed a small contrast filling close to the coils in the right lumbar artery (Fig 4). A possible increasing angulation of the stent graft was noted, but the aneurysm size was unchanged (80 mm). CDS results showed retrograde flow in the lumbar artery, reversing in diastole. Further observation for 3 months was planned, followed by repeated CT angiography and CDS.

A week before the planned control, the patient was admitted to the emergency department with acute onset back pain, hemodynamically stable but without palpable pulse in the left groin. CT scanning results showed a large endoleak from the connection between the second limb and the bifurcation, diameter increase from 80 to 100 mm, and rupture with hematoma in the retroperitoneum (Fig 5). Conventional surgical repair with a tube graft was performed without complication after explantation of the endovascular graft. The aorta initially was crossclamped above the renal arteries, and after the stent graft was removed, the clamp was

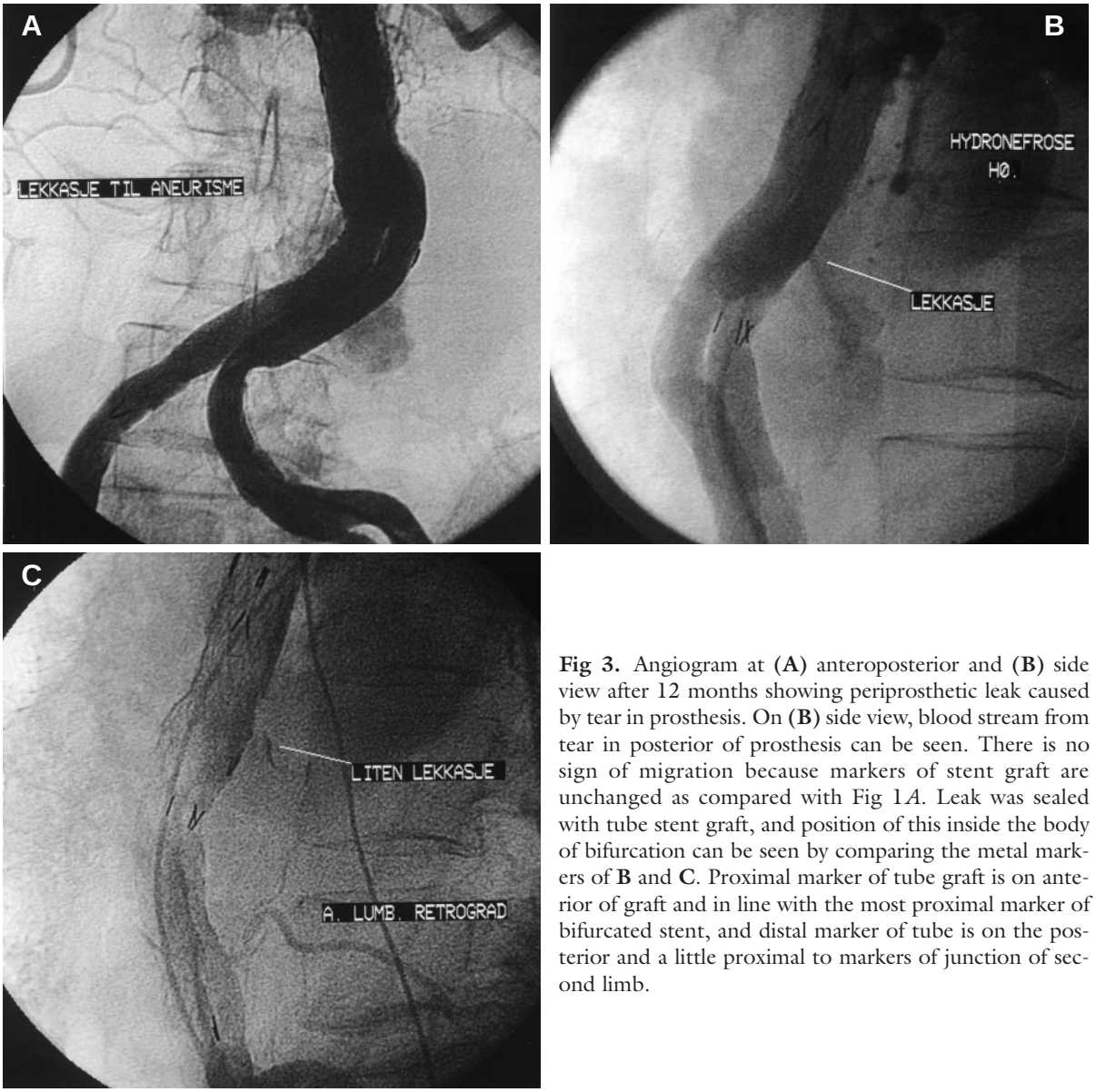

Fig 3. Angiogram at **(A)** anteroposterior and **(B)** side view after 12 months showing periprosthetic leak caused by tear in prosthesis. On **(B)** side view, blood stream from tear in posterior of prosthesis can be seen. There is no sign of migration because markers of stent graft are unchanged as compared with Fig 1*A*. Leak was sealed with tube stent graft, and position of this inside the body of bifurcation can be seen by comparing the metal markers of **B** and **C**. Proximal marker of tube graft is on anterior of graft and in line with the most proximal marker of bifurcated stent, and distal marker of tube is on the posterior and a little proximal to markers of junction of second limb.

moved to an infrarenal position and the proximal anastomosis was sutured with a standard technique. The stent graft was squeezed to reduce its diameter and was then easily removed from the infrarenal neck and the iliac arteries, and the vessel wall in these areas showed no macroscopic signs of damage or reaction to the stent. The location of the tear in the polyester prosthesis formerly shown on angiography could be confirmed (Fig 6). The postoperative course was uneventful, and the patient was doing well by November 1998.

DISCUSSION

Long-term results of endovascular repair of abdominal aortic aneurysms are still unknown. A variety of stent grafts from several manufacturers are available, each with a different design. It is known that the design of the device and the introducer system put limits on which patients are technically eligible for treatment. The significance of device design for long-term results, however, is unknown. It might be expected that the design could influence important factors, such as resistance to migration and kinking of the stent graft. All devices are a combination of metal stents with a prosthesis, either fully supported with metal through the whole length or with metal stents only in the proximal and distal attachment zones. It also differs whether the metal

Fig 4. Computed tomographic scan 3 months after embolization of lumbar arteries with backflow. There is still small backflow from right lumbar artery through coils.

Fig 5. Computed tomographic scan after 20 months. Periprosthetic leak is related to connection between second limb and bifurcation. Size of aneurysm has increased to 100 mm, and there is rupture with retroperitoneal hematoma.

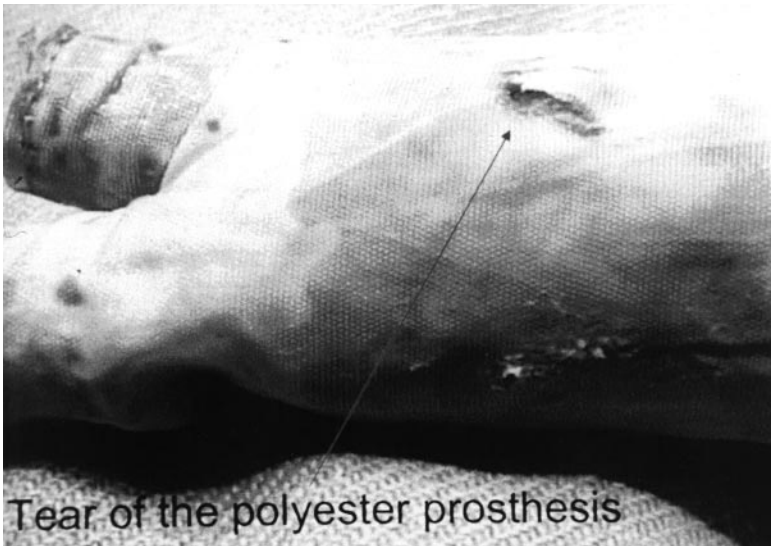

Fig 6. Explanted endovascular aortic graft. V-formed tear of polyester prosthesis was adjacent to V-formed shape of underlying nitinol wire. At this point, the suture connecting wire to more caudal zigzag wire was broken, allowing the two struts to move separately.

stents are on the inside or outside of the fabric and how the metal is attached to the fabric. Also, bifurcated stents can be designed either as one piece or with a second limb to be attached to the bifurcated part from the contralateral groin. Resistance to material fatigue can be tested in the laboratory, but most tests are designed for longitudinal and radial movements. In vivo, the stents will be angulated and sometimes twisted, and this might be important to the forces pulsation induce on the device.

Many details of design possibly could have significant influence on the long-term performance of the device. However, because of the complexity of this and the rapid development of the technique, randomized studies are difficult to perform.

The Vanguard endovascular aortic graft consists of a memory nitinol wire framework held together in a zigzag pattern by 4-0 polypropylene sutures, with a woven polyester prosthesis on the outside. The nitinol framework and the prosthesis are attached to each other proximally and distally but not in between. According to the manufacturer, breakage of the sutures holding the zigzag stents together is not uncommon. When this was discovered during the fall of 1997, product shipments were stopped while the problem was investigated. The manufacturer concluded in November 1997 in an informational letter to their customers that, even with 75% of sutures removed, the device will maintain its position and structural integrity. Penetration of the graft material by nitinol struts had never been described.

It is our opinion that, in the case report presented here, it is likely that the suture breakage that caused separation and increased mobility of the nitinol struts might have resulted in a penetration of the prosthesis and late periprosthetic leak. It seems to be important to follow patients with special care with regard to suture breakage and possible risk of penetration. In this device, the metal components can move freely related to the covering fabric. When the sutures break, there might be a risk that the apex of a zigzag stent could angle into the frabric and cause focal wear.

Detachment of the second limb of the device from the bifurcation part has been described to lead to rupture.[4] It is also important to closely follow the position of the radioopaque markers in the area of overlap between these two components. Kinking and angulation of the stent graft might increase the risk for detachment, and it is a paradox that the remodeling that occurs as the aneurysm shrinks after complete exclusion might increase the angulation of the stent graft. In our case, the stent-in-stent in the body part of the stent graft might have caused the device to be less compliant to pulsatile movements and to changes caused by remodeling, thus increasing the risk of detachment. When detachment is discovered without alarming symptoms of expanding/ruptured aneurysm or ischemic lower leg, percutaneous treatment can be considered.

There has been an increasing number of reports of rupture in patients who formerly underwent treatment with stent grafts.[5] It is not known whether all types and degrees of endoleak carry the same risk of rupture.[6] We have noted from this case that, in a situation with back and forth flow in lumbar arteries without communication to the stent graft itself, the mean pressure in the aneurysm sac was 100 mm Hg. Also, it is interesting that thin lumbar branches increased considerably in size to serve as outflow when the perforation in the stent graft occurred. At the next event of major leak from the stent graft (the detachment of the second limb), these lumbar vessels had been coil embolized in the mean time and could not serve the same purpose. This might have contributed to the rupture.

Although endovascular repair of abdominal aortic aneurysms has been shown to be safe in the short term, there are still numerous problems to be solved before it can be concluded that the method is as safe as conventional surgical repair in the long term.

ADDENDUM

In November 1998, after this manuscript was prepared, we received an important message from Boston Scientific Corporation sent to all customers. Apparently, late endoleaks caused by holes in the fabric covering now have been reported to the manufacturer in six cases, and "Investigations show that the failures are due to focal wear at the apex of a nitinol stent 'zig' against the graft fabric."

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Please see the related articles by Drs Zarins and Rutherford on pages 1164-6 and 1167-9, respectively.