Access strategies for revision or explantation of the Charité lumbar artificial disc replacement

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Background: Several lumbar disc prostheses are being developed with the goal of preserving mobility in patients with degenerative disc disease. The disadvantage of lumbar artificial disc replacement (ADR) compared with anterior interbody fusion (ALIF) is the increased potential for displacement or component failure. Revision or removal of the device is complicated by adherence of the aorta, iliac vessels, and the ureter to the operative site. Because of these risks of anterior lumbar procedures, vascular surgeons usually provide access to the spine. We report our experience with secondary exposure of the lumbar spine for revision or explanation of the Charité disc prosthesis.

Methods: Between January 2001 and May 2006, 19 patients with prior implantation of Charité Artificial Discs required 21 operations for repositioning or removal of the device. Two patients had staged removal of prostheses at two levels. One patient had simultaneous explantation at two levels. The mean age was 49 years (range, 31 to 69 years; 56% men, 42% women). The initial ADR was performed at our institution in 14 patients (74%). The mean time from implantation to reoperation was 7 months (range, 9 days to 4 years). The levels of failure were L3-4 in one, L4-5 in nine, and L5-S1 in 12. *Results:* The ADR was successfully removed or revised in all patients that underwent reoperation. Three of the 12 procedures at L5-S1 were performed through the same retroperitoneal approach as the initial access. One of these three, performed after a 3-week interval, was converted to a transperitoneal approach. Four of the L4-5 prostheses were accessed from the original approach and five from a lateral, transpoas exposure (four left, one right). The only explantation at L3-4 was from a left lateral transposas approach. Nineteen of the 22 ADR were converted to ALIF. Two revisions at L5-S1 involved replacement of the entire prosthesis. One revision at L4-5 required only repositioning of an endplate. Access-related complications included, in one patient each, iliac vein injury, temporary retrograde ejaculation, small-bowel obstruction requiring lysis, and symptomatic, large retroperitoneal lymphocele. There were no permanent neurologic deficits, deep vein thromboses, or deaths.

Conclusions: Owing to vascular and ureteral fixation, anterior exposure of the lumbar spine for revision or explantation of the Charité disc replacement should be performed through an alternative approach unless the procedure is performed ≤ 2 weeks of the index procedure. The L5-S1 level can be accessed through the contralateral retroperitoneum. Reoperation at L3-4 and L4-5 usually requires explantation and fusion that is best accomplished by way of a lateral transpoas exposure. (J Vasc Surg 2006;44:1266-72.)

During the last 15 years, the number of anterior lumbar spinal reconstructions for degenerative disc disease has significantly increased. The evolution of spine technology has changed the occasional anterior procedure through a large flank incision to commonplace fusions through a direct anterior extraperitoneal exposure. Because of the proximity of the lumbar spine to the aorta, inferior vena cava, and the iliac vessels, anterior exposures are frequently performed by vascular surgeons.

Despite high rates of radiographic fusion using cages and allografts, long-term outcomes are limited by persistent back pain, loss of mobility, and the development of adjacent level degenerative disease. These complications

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have led to the development of prostheses designed to allow normal flexion, extension, and rotation.

The first device available in the United States is the Charité artificial disc replacement (ADR), which was developed in Berlin in the mid-1980s and has been implanted worldwide in >15,000 patients.¹ A randomized trial comparing Charité ADR with anterior lumbar interbody fusion (ALIF) was completed in December 2001, and US Food and Drug Administration (FDA) approval followed in October 2004.² In the first year after FDA approval, approximately 4000 devices were implanted.³

The Charité device consists of two metal alloy endplates with a sliding polyethylene core (Fig 1). Causes of removal or revision of the prosthesis are multifactorial and are related to technical errors at implantation, use of the prosthesis for non-FDA-approved indications such as multilevel disease, and persistence of symptoms. We report our experience with explantation and revision of the Charité ADR, focusing on lessons learned that may minimize vascular and ureteral injuries.

PATIENTS AND METHODS

Patients. Between January 2001 and May 2006, 19 patients with Charité ADR devices required 21 reopera-

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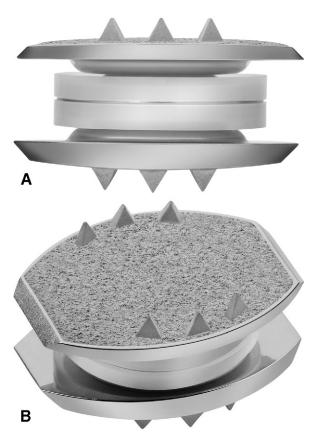


Fig 1. Charité artificial lumbar disc replacement viewed from the direct anterior (A) and superior oblique (B) perspective. Note teeth that secure endplates to the vertebral body.

tions at two hospitals for displacement (n = 18) or subsidence (n = 2) of the prosthesis or persistent biomechanical back pain despite posterior fusion (n = 1). During this period, we performed 1143 anterior thoracolumbar exposures, predominantly ALIFs for degenerative disc disease at L4-5 and L5-S1. Two patients had staged removal of prostheses at two levels, and one patient had simultaneous explantation at two levels. The mean age was 49 years (range, 31 to 69 years), and 58% were men, and 42% were women.

The initial ADR was performed in Europe before FDA approval in four patients who did not wish to be subjects in the American randomized trial of ALIF vs ADR. One patient had his disc replacement in another state. The remaining 14 patients had their implantation done by six spine surgeons at our two hospitals. The mean time from implantation to reoperation was 7 months (range, 9 days to 4 years). The levels of failure were L3-4 in one, L4-5 in nine, and L5-S1 in 12. Individual patient data are given in the Table.

Operative procedure for implantation. The skin incision varied, depending on the levels exposed, but was usually midline except for transverse incisions in women who had a single-level ADR at L5-S1. The midline fascia was incised along the medial border of the left rectus muscle. The dissection plane was continued laterally under the rectus muscle, anterior to the transversalis fascia and the peritoneum. The transversalis fascia was incised laterally, and the left portion of the peritoneum was retracted to the right. The left ureter was usually seen but was never dissected free from the peritoneal sac.

For L5-S1 exposure, the middle sacral artery and vein were divided, and the iliac vessels were retracted laterally with self-retaining retractors (Omni-Tract Surgical, St. Paul, Minn). Exposure of L4-5 usually required division of the left ascending lumbar (iliolumbar) vein. This allowed mobilization of the distal aorta and left iliac artery and vein to the right. Access to L3-4 was similar to L4-5 with additional division of segmental vessels crossing the body of L3.

The disc spaces at each level were widely exposed with retractor blades positioned laterally to the sympathetic chains, on the downward slope of the vertebral bodies. During the last 6 months, we have routinely placed a polytetrafluoroethylene (PTFE) patch over the implanted prosthesis to potentially facilitate secondary revision.

Operative procedure for reoperation. The approach varied, depending on the timing of the re-exploration, the level of exposure, and our accumulated experience. Initially, all re-explorations were performed through the original anterior approach. Three of the 12 reoperations at L5-S1 were performed through the standard left retroperitoneum. Two of these were accomplished ≤ 2 weeks after the index procedure. The third was converted to a transperitoneal exposure 3 weeks after implantation of the prosthesis owing to dense adhesions between the peritoneum and the abdominal wall. The remaining nine exposures of L5-S1 were through a contralateral right retroperitoneal approach using the initial skin incision. This approach mirrors the technique used for the primary exposure.

Early in our experience, we attempted to revise the ADR at L4-5 through the initial approach. Adherence of the iliac vessels to the spine prevented sufficient exposure to safely replace the entire prosthesis anteriorly. Four of the L4-5 prostheses were accessed from the original approach and five from a direct lateral transpsoas exposure (4 left, 1 right). The transpsoas approach provided adequate access to the lateral disc space to remove the prosthesis and perform a fusion at both L4-5 and L3-4. The side of the approach is determined by any lateral malpositioning of the prosthesis. Because neither the aorta nor the vena cava is mobilized for this exposure, either side is safe and provides similar exposure.

After induction of anesthesia, the patient is placed in the direct lateral decubitus (90°) position. The target disc space is identified with fluoroscopy and marked on the skin (Fig 2). In most cases, the patient is repositioned with the elevated kidney rest under the appropriate level to open the space between the iliac crest and the costal margin. An 8-cm to 10-cm transverse skin incision centered over the target disc is made between the anterior and posterior axillary lines. When the L4-5 disc space is below the iliac crest, an oblique incision is made 1 cm above the crest.

Age/sex	Index levels	Level of failure	Time to revision	Approach	Procedure	Exposure complications
40M	L4-5 & L5-S1	L5-S1	2 months	Contralateral anterior	L5-S1 ALIF	Temporary retrograde ejaculation
31M	L5-S1	L5-S1	21 days	Transperitoneal	L5-S1 ALIF & PSF	Left iliac vein injury
46M	L5-S1	L5-S1	12 days	Contralateral anterior	L5-S1 ALIF & PSF	None
49F	L5-S1	L5-S1	21 days	Contralateral anterior	L5-S1 revision ADR	None
53M	L4-5 & L5-S1	L5-S1	2 weeks	Contralateral anterior	L5-S1 revision ADR	None
50F	L5-S1	L5-S1	13 days	Ipsilateral anterior	L5-S1 ALIF & PSF	None
$51F^{\dagger}$	L4-5 & L5-S1	L5-S1	11 months	Contralateral anterior	L5-S1 ALIF & PSF	None
51F	L5-S1	L5-S1	4 years	Contralateral anterior	L4-5, L5-S1 ALIF & PSF	None
69M	L5-S1	L5-S1	11 days	Contralateral anterior	L5-S1 ALIF & PSF	None
49M	L5-S1	L5-S1	14 months	Contralateral anterior	L5-S1 ALIF & PSF	Small-bowel obstruction
$56F^{\dagger}$	L4-5 & L5-S1	L5-S1	2 months	Contralateral anterior	L5-S1 ALIF & PSF	None
50F	L4-5 & L5-S1	L4-5 & L5-S1	9 days	Ipsilateral anterior	L4-5 & L5-S1 ALIF & PSF	Retroperitoneal lymphocele
52M	L4-5	L4-5	2 months	Ipsilateral anterior	L4-5 ALIF & PSF	None
40M	L4-5	L4-5	14 months	Right lateral (transpsoas)	L4-5 ALIF & PSF	None
37F	L4-5 & L5-S1	L4-5	2 months	Ipsilateral anterior	L4-5 revision ADR	None
54F	L4-5 & L5-S1	L4-5	11 days	Ipsilateral anterior	L4-5 ALIF & PSF	None
$51F^{\dagger}$	L4-5 & L5-S1	L4-5	6 months	Left lateral (transpsoas)	L4-5 ALIF & PSF	None
$56F^{\dagger}$	L4-5 & L5-S1	L4-5	2 months	Left lateral (transpsoas)	L4-5 ALIF & PSF	None
42M	L4-5	L4-5	24 months	Left lateral (transpsoas)	L4-5 ALIF & PSF	None
55M	L4-5	L4-5	12 months	Left lateral (transpsoas)	L4-5 ALIF & PSF	None
54M	L3-4	L3-4	6 months	Left lateral (transpsoas)	L3-4 ALIF & PSF	None

Table. Patient characteristics, levels of anterior lumbar disc replacement and revision, operative approach, and complications*

ALIF, Anterior interbody lumbar fusion; PSF, posterior spinal fusion; ADR, artificial disc replacement.

*Patients are listed by level of revision and secondarily in chronologic order.

[†]Patients who had staged multilevel procedures.

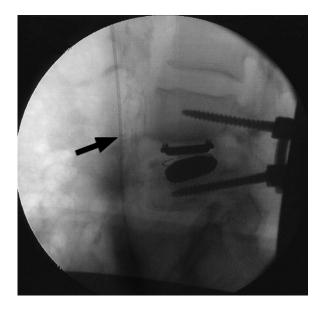


Fig 2. Lateral image of ureteral (*arrow*) and L4-5 disc space demonstrate anterior location of ureter during transpoas exposure.

The abdominal muscles are split in the direction of their fibers. The peritoneum is retracted medially to expose the psoas muscle. The disc spaces can be palpated as raised ridges medial to the psoas muscle. After fluoroscopic confirmation of the correct level, the psoas muscle is bluntly divided longitudinally. Electrocautery is necessary to release attachments of the muscle to the spine but should be limited owing to proximity to nerve roots.

The renal vein blades of the retractor system are used to maintain exposure while the disc space is entered and the spine surgeon retrieves the prosthesis. Ureteral stents were placed before two of the late anterior re-exposures and two of left lateral access at L4-5. We no longer use ureteral stents for the transposas approach because the ureters are sufficiently anterior to the plane of dissection to avoid injury. Only one patient (L5-S1) has had anterior reoperation since routine placement of a PTFE patch over the prosthesis. Although there was a significant inflammatory rind over the patch, longitudinal division of the PTFE facilitated mobilization of the adjacent iliac veins.

RESULTS

The Charité prosthesis was successfully revised or removed in all patients that underwent reoperation. Anterior re-exposure of L5-S1 was sufficiently wide to allow replacement with a smaller prosthesis in two patients. The other 10 ADR at L5-S1 were converted to ALIF. Only one patient had revision at L4-5. This patient fell 2 months after her ADR, resulting an anterior displacement of the superior endplate of 2 to 3 mm. Although anterior exposure was difficult, the endplate could be repositioned through a limited exposure. The remaining eight patients with L4-5 and one patient with L3-4 prostheses were converted to ALIF.

Ureteral stents were placed prophylactically in four patients having revision at L4-5. There were no ureteral complications. One gastrointestinal complication occurred in a patient who had re-exposure at L5-S1 through a contralateral retroperitoneal approach. Although the peritoneum was not violated, a small bowel obstruction developed 3 weeks later that required exploration at another institution. In one patient who had transperitoneal conversion at L5-S1, an iliac vein injury occurred during removal of the prosthesis. This was repaired primarily without sequelae.

One obese patient fell while leaving the hospital after ADR at L4-5 and L5-S1. At the time of reoperation, she was found to have a large lymphocele from the division of abundant retroperitoneal soft tissue at her initial procedure. This fluid collection reaccumulated, causing significant pain and anorexia. Computed tomographic urography showed moderate proximal hydronephrosis without extravasation and fluid analysis (fluid creatinine 0.4 mg/dL) was inconsistent with ureteral injury. The patient's symptoms and hydronephrosis resolved after laparoscopic marsupialization of the lymphocele (Fig 3).

In the first patient in our series, whose initial surgery was a multilevel ADR in Europe, retrograde ejaculation developed after removal of the L5-S1 prosthesis and ALIF. His sexual function returned to normal over several months.

There were no deep vein thromboses, permanent neurologic complications, or deaths. The transposa approach was not associated with any neurologic morbidity.

DISCUSSION

Spinal fusion surgery has been increasing steadily during the last decade. Between 1996 and 2001, the number of spinal fusions in the United States rose by 77%.⁴ Multiple factors may explain this increase, including changes in the population, advances in spinal imaging and surgical technique, and the development of human recombinant bone morphogenetic protein, which obviates the harvest of iliac crest donor bone. Coincident with the rise in fusions was the FDA approval of threaded intervertebral cages. Many of these devices were designed to be placed through a direct anterior lumbar approach.⁵

A recent meta-analysis of surgical approach for isthmic spondylolisthesis indicated a superiority of combined anterior and posterior procedures in achieving fusion and successful clinical outcome.⁶ Laparoscopic approaches were popularized in the mid-1990s⁷⁻⁹ but have declined in recent years owing to increased risks of vascular injury and retrograde ejaculation, prolonged operating time, and increased expenses relative to open, retroperitoneal access.¹⁰⁻¹³ The rapid increase in anterior spine surgery has created a demand for access surgeons familiar with retroperitoneal procedures and skilled at mobilizing vessels.¹⁴⁻¹⁶

Lumbar fusion is intended to alleviate pain by eliminating motion. Unfortunately, successful fusion may result in degeneration of adjacent level discs.^{17,18} Reoperations at

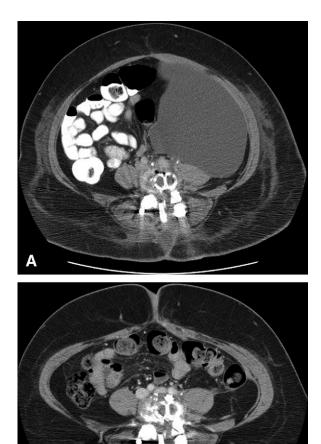


Fig 3. A, Large retroperitoneal lymphocele that developed after initial anterior exposure of L4-5 and L5-S1 and expanded after re-exposure for removal and anterior lumbar interbody fusion. **B,** One month after laparoscopic marsupialization, the fluid collection completely resolved.

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levels adjacent to a lumbar fusion have been reported at 20% to 36% during long-term follow-up of 7 to 10 years.^{19,20} In addition, a radiographically successful fusion may not eliminate pain or restore function.²¹ Analogous to knee and hip replacement, ADR was designed to eliminate pain from degenerative disc disease while restoring normal motion.

The Charité ADR is the first lumbar device approved in the United States. The current generation of this device has been implanted in Europe since 1987. Long-term European data show good or excellent clinical outcome rates of 90%, with 92% of patients returning to work.²²⁻²⁴ A prospective, randomized, multi-institutional trial of Charité ADR vs ALIF showed that ADR patients recovered faster and were significantly more satisfied with their treatment. ADR was associated with shorter hospital stays, comparable perioperative complication rates, and lower rates of reoperation at 2 years.² Access-related complications are frequently the most serious problems encountered with either ADR or ALIF. Many spine surgeons have avoided anterior lumbar procedures because of this concern. Iatrogenic major arterial or venous injuries occur in 2% to 5% of anterior lumbar exposures.^{2,25-28} The risk of vascular injury is higher at L4-5 than L5-1 (6.2% vs 1.2%) and is increased tenfold by the instrumentation used to place threaded devices, such as fusion cages.^{26,28} Vascular injuries during the initial anterior lumbar procedure are not usually due to the exposure, but are more likely to occur during placement of cages or grafts.²

Toe pulse oximetry and somatosensory evoked potentials (SSEP) are useful indicators of arterial thrombosis.^{26,29} We frequently see transient changes in left leg SSEP with prolonged arterial retraction that does not cause any postoperative deficit. Deep vein thrombosis and pulmonary emboli that occur after 1% or 2% of major reconstructive spine operations are more common after anterior lumbar surgery.^{27,30,31}

The reported incidence of retrograde ejaculation in men is 0.4% to 8%³²⁻³⁴ and is related to the method of exposure. During open retroperitoneal access, the sympathetic nerve-bearing tissue is bluntly retracted medially along with the peritoneal sac. Laparoscopic or open transperitoneal exposure frequently causes division of the superior hypogastric plexus, with a resulting increase in sexual dysfunction.^{9,13,35} Repeat exposure of the lumbar spine from a direct anterior approach significantly increases the risk of retrograde ejaculation. The nerve-bearing tissue that was previously retracted medially is now adherent to the operative field. The patient in our series who experienced temporary retrograde ejaculation had a contralateral retroperitoneal exposure of L5-S1. Although the dissection down to the disc space was not difficult, it is likely that retrograde ejaculation resulted from the cumulative effect of bilateral mobilization of sympathetic fibers. The lateral transpsoas exposure has not been associated with this risk of sexual dysfunction.

Ureteral injuries are infrequently documented in case reports or small series of anterior lumbar procedures.^{16,36,37} A retrospective review of 471 ALIF procedures found one ureteral injury (0.2%).²⁸ We had a single ureteral injury in our current series of 1143 anterior thoracolumbar exposures performed for a variety of indications, including degenerative disc disease, scoliosis, trauma, and infection. The ureter was damaged by a screw placed from the posterior approach that traversed the vertebral body during a primary anteroposterior fusion, unrelated to the anterior exposure.

The incidence of complications that require revision or removal of Charité ADR is uncertain. Lemaire et al²³ reported 107 patients after a minimum of 10-year follow-up with no explants. In the American multi-institutional trial, the revision and removal rates of 205 patients at 2 years were 2.4% and 1%, respectively.² Yet the rapid proliferation of this technology in the last 2 years will certainly result in many secondary anterior operations.

There is a paucity of reported experience with ADR revision and removal. The rapid scarring that fuses the iliac vessels and the left ureter to the spine and obscures their margins imposes significantly higher risk of complications during these secondary procedures. Complete replacement of an ADR requires significant side-to-side access to the spine. Replacement of the device is much more feasible at L5-S1 than L4-5 or L3-4. The contralateral retroperitoneal approach to L5-S1 is still limited by adherence of the iliac vessels to the spine. We use primarily blunt dissection to identify the medial border of the common iliac vein and to mobilize the vein just enough to permit removal and replacement of the prosthesis. Sharp dissection is perilous owing to the indistinct borders of the vascular structures. The advantage of the contralateral approach is an undisturbed plane back to the spine that makes ureteral and vascular injuries less likely. A transperitoneal approach to L5-S1 requires a larger incision, results in a longer postoperative ileus, and is associated with a higher rate of retrograde ejaculation. The iliac bone prevents the direct lateral exposure used on more cephalad levels.

Even procedures performed between 1 and 2 weeks postoperatively may not allow sufficient exposure of L4-5 to replace the ADR with a new prosthesis. Therefore, after 2 weeks, device dislocation or subsidence that requires revision at L3-4 or L4-5 is best treated by removal and fusion through a lateral access. This is a modification of an endoscopic approach used for primary anterior lumbar fusion previously reported from our institution.³⁸

Before the advent of ADR, we preferentially used the lateral transpoas approach for obese patients who need ALIF at L2-3 or L3-4. The incision used for this access is significantly shorter than the large flank incisions common more than a decade ago. Denervation injuries that result in muscle bulging and patient dissatisfaction have not been observed with this technique. The transpoas approach provides an undisturbed plane to reach the lateral disc space without significant risk of vascular or ureteral injury.

An inflammatory rind rapidly forms over the disc prosthesis, which separates the device from the overlying vessels. Similar to results reported with primary anterior fusion, vascular injury during the lateral approach is more likely to occur during instrumentation to extract the ADR and place an allograft or other devices than during the exposure. Fluoroscopic visualization of the stent during lateral exposure shows that the operative field is significantly posterior to the course of the ureter. We no longer use ureteral stents in patients who undergo transpsoas access for Charité removal; however, we believe that when the anatomy or indications mandate anterior re-exploration through the original approach, stents may have merit.

We have not encountered any difficulty removing the prosthesis from either the left or the right lateral approach. The only disadvantage of the transpoas exposure is the potential for local nerve trauma. Bergey et al³⁸ documented a 30% incidence of postoperative transient groin or thigh discomfort, or both, due to genitofemoral nerve irritation, which usually resolves after 4 weeks. This complication only

occurred in patients who had multiple level exposures and was not seen in the current series. It is also important to dissect through the anterior one third of the psoas muscle to avoid nerve root injury. Intraoperative neurologic surveillance is particularly important at the L4-5 level where the L3 nerve root may traverse the disc space when approached laterally.

The Charité ADR endplate has small teeth that are easily dislodged from a lateral approach. Newer designed lumbar prostheses, such as the ProDisc (Synthes, West Chester, Pa) and Maverick (Medtronic Sofamor Danek, Memphis, Tenn) ADR, have large midline keels that may prevent lateral removal.

Bertagnoli et al³⁹ have suggested several strategies to facilitate revisions. The first is a "strategic" approach to keep the left L4-5 region undisturbed for future surgery. He recommended that index operations at L5-S1 be done from the right side, with revisions performed through a transperitoneal approach. This leaves the left retroperitoneum available for more proximal level access in the future. Another strategy, which we independently adopted in mid-2005, is placement of an antiadhesive membrane (PTFE) between the vessels and the prosthesis. We have reoperated anteriorly on one patient with an L5-S1 prosthesis after this technique. In this case, once the PTFE was encountered, the dissection of the ADR from the iliac vessels appeared easier than in prior cases. Finally, Bertagnoli et al have recommended that future prostheses should have a modular design that would allow revision through a limited exposure or placement through a lateral approach that may be easier to revise.

CONCLUSION

Malposition or dislocation of Charité lumbar disc prostheses that require revision ≤ 2 weeks can usually be exposed through the same anterior retroperitoneal access. Later revisions at L5-S1 should be undertaken through a similar right retroperitoneal approach. Scarring and fixation of the vessels and the left ureter limit anterior exposure of proximal lumbar levels after 2 weeks. In most cases, explantation of the prosthesis and fusion through a lateral transpsoas approach is the best option for devices at L4-5 and above. Placement of a PTFE membrane over the prosthesis at the index procedure may prevent adhesion of the vessels to the spine and allow safer anterior revision.

AUTHOR CONTRIBUTIONS

Conception and design: WW, JR Analysis and interpretation: WW, SL, JR Data collection: WW, JR, SL, TL, RR Writing the article: WW Critical revision of the article: WW, JR, SL, PJ, DC Final approval of the article: WW Statistical analysis: Not applicable Obtained funding: Not applicable Overall responsibility: WW

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