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The Charité Artificial Disc: Insertion Technique

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The Charité Artificial Disc is the first commercially available motion-preserving technology for the lumbar spine (Fig. 1). The Charité is the first US Food and Drug Administration (FDA)–approved artificial disc for the treatment of single-level lumbar degenerative disc disease (DDD) from L4 to S1. With thousands of implantations worldwide since 1987, it has the longest clinical experience of any artificial disc. Preclinical testing indicates that the mobile core design is intended to maintain motion of the operative spinal segment [1]. With a large array of implant sizes and heights with variable built-in lordosis, an appropriate implant can be customized to the patient's anatomy. The design of the Centreline TDR instruments (Raynham, Massachusetts) provides for accurate sizing and efficient placement of the Charité Artificial Disc. The artificial disc incorporates a durable and robust design for short-term and long-term stability. Extensive preclinical animal [2,3], biomechanical [1], and wear debris [4] testing in conjunction with the Investigational Device Exemptions clinical study in the United States [5] and experience around the world [6–11] has proven that the Charité Artificial Disc is safe and effective for the treatment of lumbar DDD (Tables 1–6). No other artificial disc has the substantial preclinical and clinical history that validates its use.

The Charité Artificial Disc is composed of proven orthopedic materials; cobalt chromium end plates and an ultrahigh-molecular-weight polyethylene (UHMWPE) sliding core. Preclinical testing indicates that the mobile core design incorporates a floating center of rotation (COR), enabling independent translation and rotation, which are key components of physiologic motion. The mobile core moves dorsally during flexion and ventrally during extension.

The Charité Artificial Disc System includes an extensive range of core heights, end plate sizes and end plate angles, providing the surgeon with numerous options to help ensure proper sizing, placement, and segmental lordosis. The Centreline TDR instrumentation aids in midline placement for optimal performance. Preclinical testing indicates that this system is designed to do the following:

- Maintain motion of the operative spinal segment
- Maintain segmental stability
- Restore proper disc height
- Re-establish lordotic alignment

The treatment of lumbar DDD does not depend solely on the Charité Artificial Disc, however. Other important considerations include the following:

- Completion of a company-sponsored training program on use of the Charité Artificial Disc and Centreline TDR instruments
- Proper patient selection
- Safe and adequate surgical approach and exposure to the appropriate degenerative disc level
- Complete discectomy and meticulous end plate preparation
- Optimal implant size, height, and lordosis selection and proper placement

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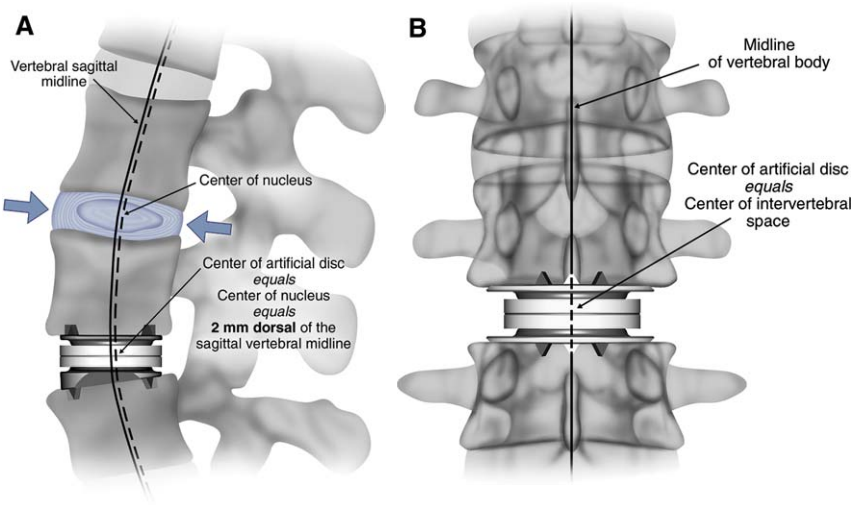

Fig. 1. (*A, B*) Charité artificial disc.

Indications for use

The Charité Artificial Disc is indicated for spinal arthroplasty in skeletally mature patients with DDD at one level from L4 to S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients with DDD should have no more than 3 mm of spondylolisthesis at the involved level. Patients receiving the Charité Artificial Disc should have failed at least 6 months of conservative treatment before implantation of the Charité Artificial Disc.

Table 1
Approach-related complications

Complication	Investigational (n = 205)	Control (n = 99)	*P* value
Approach-related [n (%)]	20 (9.8)	10 (10.1)	0.9247
Venous injury	9 (4.4)	2 (2.0)	
Retrograde ejaculation[a]	3 (3.3)	3 (5.5)	0.5154
Ileus	2 (1.0)	1 (1.0)	
Perioperative vein thrombosis	2 (1.0)	0	
Clinically significant blood loss >1500 mL	1 (1.0)	2 (2.0)	
Incisional hernia	1 (0.5)	2 (2.0)	
Epidural hematoma	1 (0.5)	0	
Dural tear	1 (0.5)	0	
Deep vein thrombosis	0	0	
Arterial thrombosis	0	0	

[a] Of 92 men in the investigational group and 55 men in the control group.

From Blumenthal S, McAfee P, Guyer R, et al. Prospective, randomized, multicenter comparison of artificial disc vs. fusion for single level lumbar degenerative disc disease: a two-year follow-up study. Presented at the 19th Annual Meeting of the North American Spine Society (NASS). Chicago, 2004; with permission.

Table 2
Infection

Complication	Investigational (n = 205)	Control (n = 99)	*P* value
Infection [n (%)]	26 (12.7)	8 (8.1)	0.2328
Superficial wound with incision site Pain	13 (6.3)	2 (2.0)	0.1031
Other nonwound related	5 (2.4)	1 (1.0)	
Urinary tract infection	5 (2.4)	1 (1.0)	
Wound swelling	2 (1.0)	0	
Pulmonary	1 (0.5)	0	
Peritonitis	0	1 (1.0)	
Graft site	0	3 (3.0)	

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Table 3
Neurologic

Complication	Investigational (n = 205)	Control (n = 99)	*P* value
Neurologic [n (%)]	33 (16.1)	17 (17.2)	0.8128
Major [n (%)]	9 (4.4)	4 (4.0)	0.8876
Burning or dysthetic pain	5 (2.4)	3 (3.0)	
Motor deficit: index level related	3 (1.5)	1 (1.0)	
Nerve root injury	1 (0.5)	0	
Minor [n (%)]	20 (9.8)	8 (8.1)	
Numbness: index level related	20 (9.8)	7 (7.1)	
Numbness lower sacral root distribution	0	1 (1.0)	
Other [n (%)]	8 (3.9)	8 (8.1)	
Numbness: non–index level related	5 (2.4)	4 (4.0)	
Reflex change	2 (1.0)	2 (2.0)	
Positive Wadell sign	1 (0.5)	1 (1.0)	
Mechanical signs (SLR)	0	1 (1.0)	

Abbreviation: SLR, straight leg raise.

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Preoperative planning

A thorough preoperative plan is critical. Before performing any artificial disc surgery, the following steps are recommended:

- Perform a thorough review of preoperative patient radiographs to identify any possible contraindications to disc replacement and to gain a preoperative estimate of the implant size and angle. Preoperative evaluation of the patient's history, symptoms, and radiologic studies need to verify that the suspect lumbar disc is the significant pain generator. Often, discograms or diagnostic blocks are necessary to verify the site(s) of pain generation.
- Coordinate with a vascular or general surgeon trained as a spinal access surgeon (Fig. 2).
- Place the patient on a radiolucent operating table that allows for C-arm movement. Intraoperative adjustability of lordosis using a

Table 4
Fusion treatment–related/device-related/reoperation index level

Complication	Investigational (n = 205)	Control (n = 99)	*P* value
Fusion treatment related [n (%)]	0	27 (27.3)	
Nonunion/ pseudarthrosis	0	9 (9.1)	
Bone graft donor site pain	0	18 (18.2)	
Prosthesis related [n (%)]	8 (3.9)	1 (1.0)	0.1632
Collapse or subsidence of implant into adjacent vertebrae	7 (3.4)	1 (1.0)	
Implant displacement	1 (0.5)	0	
Additional surgery index level [n (%)]	11 (5.4)	9 (9.1)	0.1271
Revision	5 (2.4)	0	
Reoperation	4 (2.0)	8 (8.1)	
Removal	2 (1.0)	1 (1.0)	

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Table 5
Other complications

Complication	Investigational (n = 205)	Control (n = 99)
Other [n (%)]	9 (4.4)	4 (4.0)
Adjacent level degenerative disc disease	2 (1.0)	1 (1.0)
HNP adjacent level	2 (1.0)	1 (1.0)
Spondylolisthesis	1 (0.5)	1 (1.0)
Spinal stenosis	1 (0.5)	0
Annulus ossification	1 (0.5)	0
Calcification resulting in bridging trabecular bone	1 (0.5)	0
Other lumbar degenerative	1 (1.0)	0
Facet joint degeneration	0	1
Death, narcotic related	1 (0.5)	0

Abbreviation: HNP, herniated nucleus pulposus.

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Table 6
Surgical data comparison

Variable	Investigational (n = 205)	Control (n = 99)	*P* value
Operative time (min)			
Mean	110.8 (47.7)	114.0 (67.9)	0.6277
Median (Std)	99.0	87.0	
Range	42–300	40–410	
Blood loss (mL)			
Mean (Std)	205.0 (211.7)	208.9 (283.9)	0.8948
Median	150.0	100.0	
Range	10–1500	20–2000	
Duration of hospitalization (days)			
Mean (Std)	3.7 (1.18)	4.2 (1.99)	0.0039
Median	4.0	4.0	
Range	1–11	2–16	
1–2 days [n (%)]	21 (10.2)	7 (7.0)	0.1177
3 days [n (%)]	67 (32.7)	29 (29.3)	
4 days [n (%)]	87 (42.4)	36 (36.4)	
5 days [n (%)]	18 (8.8)	14 (14.1)	
6–7 days [n (%)]	8 (3.9)	8 (8.1)	
>7 days [n (%)]	3 (1.5)	5 (5.1)	
Missing [n (%)]	1 (0.5)	0	
Treatment levels [n (%)]			
L4–L5	61 (29.8)	32 (32.3)	0.6910
L5–S1	144 (70.2)	67 (67.7)	

Fisher exact test was used to test categoric variables, and student *t* test was used to test means.

Abbreviations: min, minutes; Std, standard deviation.

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hinged table or inflatable pillow is often useful during implant placement.

Patient positioning

- Place the patient in a supine position on a folding table or over an inflatable pillow (Fig. 3A).
- Align the break in the table or the inflatable pillow directly under the affected disc.
- The disc space can now be opened by breaking the table (or inflating the pillow) to extend and/or increase lordosis of the spine or closed by flattening the table (or deflating the pillow) to flex and/or decrease lordosis of the spine.

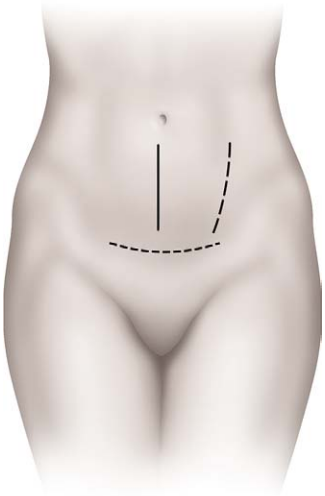

Fig. 2. Incision.

- Position the patient's upper limbs so that there is space for circumferential C-arm movement over and around the operative level.

Surgical approach

- Make a left paramedian skin incision (see Figs. 2 and 3B).
- Retract the underlying subcutaneous tissue until the fascia is exposed. Divide longitudinally with dissecting scissors.
- Retract the left rectus muscle to the left with fingers or blunt retractors (Fig. 3C).
- Raise the underlying fascia. Divide longitudinally with dissection scissors or blunt dissection (Fig. 4A).
- Identify the psoas, iliac artery, and iliac vein (Fig. 4B).

Approach of L5 to S1

- Expose the L5-to-S1 intervertebral disc and ligate the median sacral vessels.
- Further dissection of the tissue anterior to the intervertebral disc is mainly by blunt dissection. Careful attention to dissection and avoidance of electrocautery are advised. This dissection is carried first to the left and then to the right to achieve the maximum possible lateral exposure of the disc.

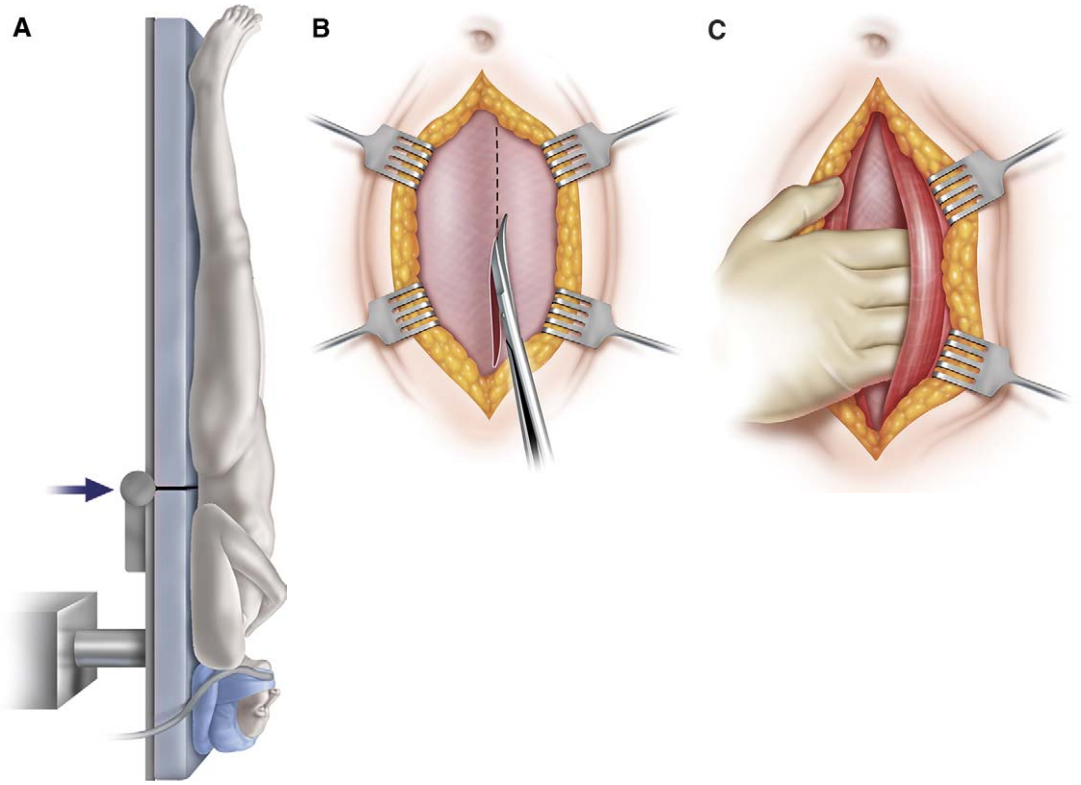

Fig. 3. (*A–C*) Surgical approach and positioning.

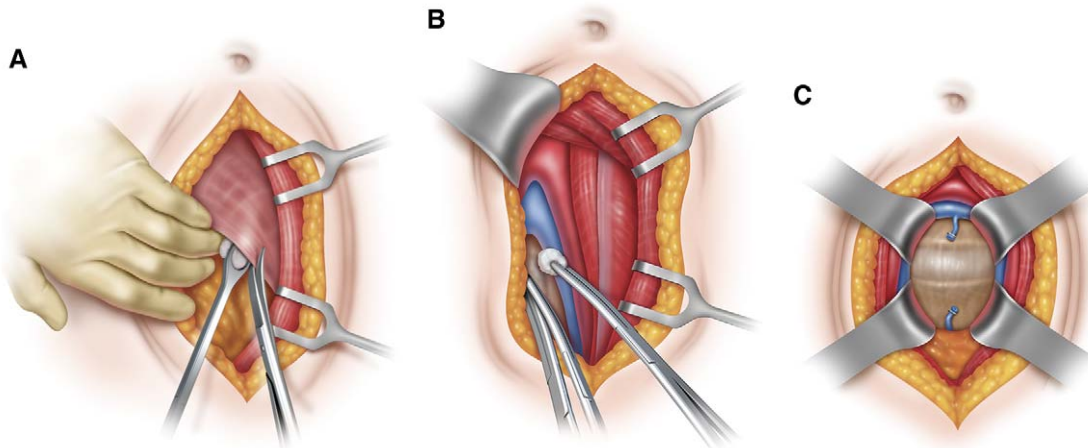

Fig. 4. (*A–C*) Surgical approach.

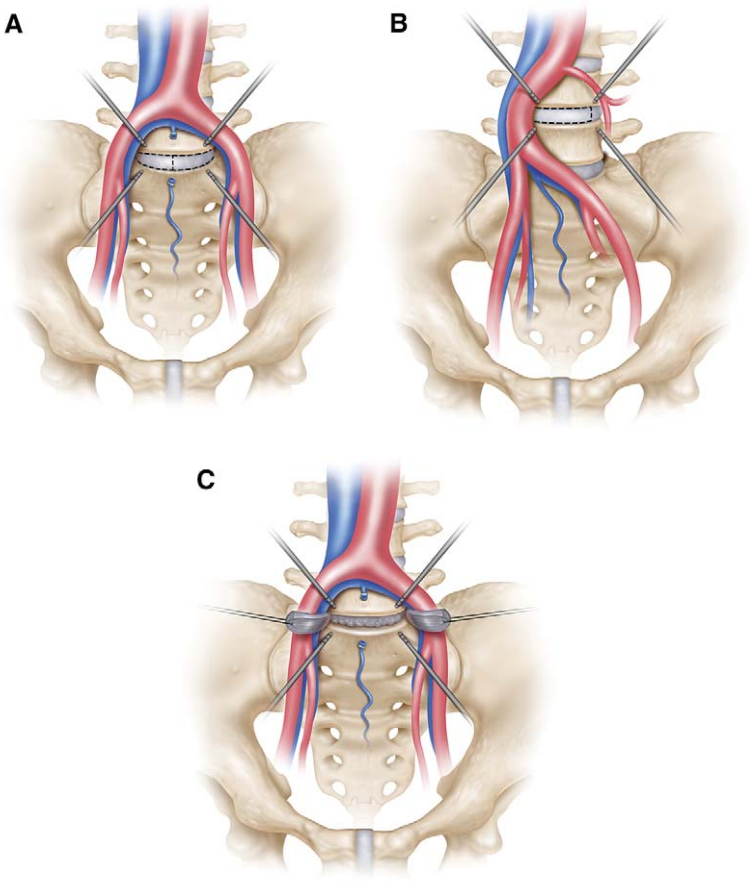

Fig. 5. (*A–C*) Surgical approach.

- Extreme care should be taken to protect the left and right common iliac vessels.
- Bluntly mobilize the left common iliac vein and artery with small swabs and then the right common iliac artery together with the right common iliac vein that lies posterior.
- All these vessels are retracted laterally and occasionally slightly superiorly (Fig. 4C).
- Carefully impact four retractor pins into the adjacent vertebral bodies, or use an appropriate external soft tissue retractor system (Fig. 5A).
- Verify the vertebral level by lateral fluoroscopy.
- Use a midline incision to open the anterior annulus. The flaps may be used for protection of eccentric vessels.
- Mobilize the iliac vein, iliac artery, vena cava, and aorta to the right. Carefully impact four retractor pins into the adjacent vertebral bodies, or use an appropriate external soft tissue retractor system (Fig. 5B).
- Verify the vertebral level by lateral fluoroscopy.
- Use a leftward incision to open the anterior annulus. The flap may be used for protection of eccentric vessels.
- If desired, hold the annulus fibrosus in position with a suture and mosquito clamp (Fig. 5C).

Complete discectomy

Performing a complete discectomy is critical for implantation. A complete discectomy, including the removal of the posterior lateral recesses of the disc, facilitates the following:

- Parallel distraction, which allows for the restoration of intervertebral height and sufficient opening of the neuroforamen

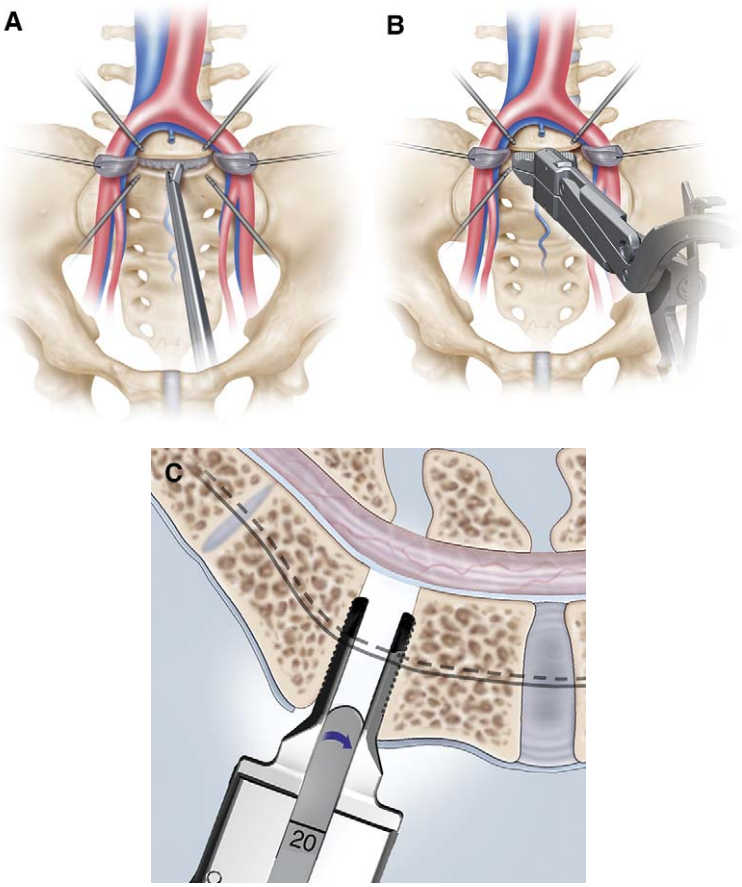

Fig. 6. (*A–C*) Discectomy.

- Parallel alignment of the inner surfaces of the end plates, which provides uniform loading of the UHMWPE sliding core
- Sufficient space for the largest sized Charité Artificial Disc possible
- Sequentially distract the disc space using the spacers and modular T-handle through the spreading tips. Parallel distraction is critical for restoration of disc height and sufficient opening of the neuroforamen.

Discectomy technique

- Perform the initial central discectomy using rongeurs, curettes, or a disc elevator (Fig. 6A).
- Care must be taken not to damage the bony end plate.
- Apply controlled distraction using the spreading and insertion forceps to visualize and remove the remaining disc tissue, leaving only the lateral annulus (Fig. 6B, C).
- It is imperative to remove the posterior lateral recesses of the disc and to release the posterior annulus.

End plate preparation

- Remove the cartilaginous end plate with the curettes using a side-to-side motion (Fig. 7).
- Care must be taken not to damage the bony end plate.
- When necessary, carefully shape curved vertebral surfaces by removing dorsal and ventral osteophytes using the curettes and rongeurs or other appropriate instruments to ensure optimal placement of the Charité Artificial Disc.
- Preservation of the integrity of the cortical end plate of the vertebral body is imperative

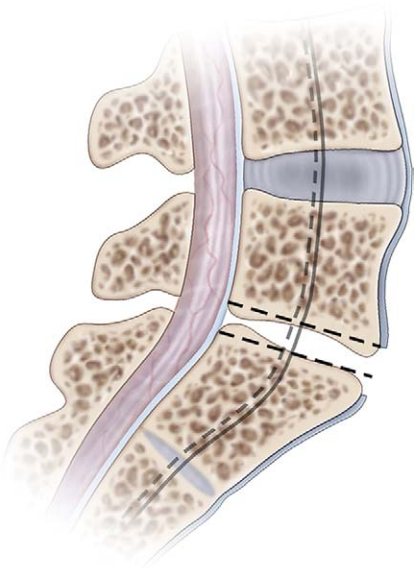

Fig. 7. End plate preparation.

because the preserved end plate provides a firm base for mechanical stability and reduces the potential for subsidence.

Fluoroscopy

Achieving a good anteroposterior (AP) film to define the midline of the vertebral body is critical to proper placement of the device. Positioning the fluoroscopic radiographic machine at the correct angle and position to get a good AP film can be challenging but worth the effort in time and patient outcome. Positioning fluoroscopy so that the pedicles are of equal size and magnification as well as equidistant from the spinous process is a good tip to aid in placement of the trial and midline markers.

Implantation trialing

- Determine the correct footprint size using the sizing gauges, which correspond to end plate footprints. Verify the correct size by lateral fluoroscopy.
- Insert the trial insertion guide into the disc space, placing the ''marker side'' superior.
- Insert the loaded trial insertion instrument through the trial insertion guide to distract and place the trial (Fig. 8A–C).
- Remove the trial insertion guide from the disc space, leaving only the trial.
- Proper size, placement, and lordotic angulation are imperative.
- Verify the correct footprint size, placement, and lordotic angle by AP and lateral fluoroscopy. Remove the trial insertion instrument from the trial, leaving the trial in the disc space. Take an AP radiograph. The trial is centered in the AP plane when the AP marker appears as a plus sign aligned with the spinous process (Fig. 8D, E).
- Take a lateral radiograph. The hole in the trial represents the COR. To ensure that the COR is placed in the optimal location, the COR marker should appear as a full circle 2 mm dorsal to the lateral midline.

Midline identification

Proper midline identification is critical to the success of any artificial disc procedure. The prosthesis must be placed accurately in the AP and lateral planes to place the Charité Artificial Disc, and thereby the COR, in the physiologically optimal location.

- Once the correct placement of the trial is verified, insert the midline marker into the AP midline of the superior vertebral body by placing the loaded marker inserter into the grooves on the trial insertion instrument (Fig. 9).
- The midline marker aids in the correct placement of the instruments and Charité Artificial Disc.
- Remove the trial insertion instrument and trial.

Confirming positioning

- It is critical to have shaped any curved vertebral surfaces before pilot driver impaction to reduce the potential for vertebral body or end plate fracture during pilot driver impaction.
- Accurately align the pilot driver with the midline marker. Carefully impact the pilot driver that corresponds to the chosen footprint to verify the ability to place the end plates accurately into the proper position. The center of the pilot driver should be 2 mm dorsal to the lateral midline.

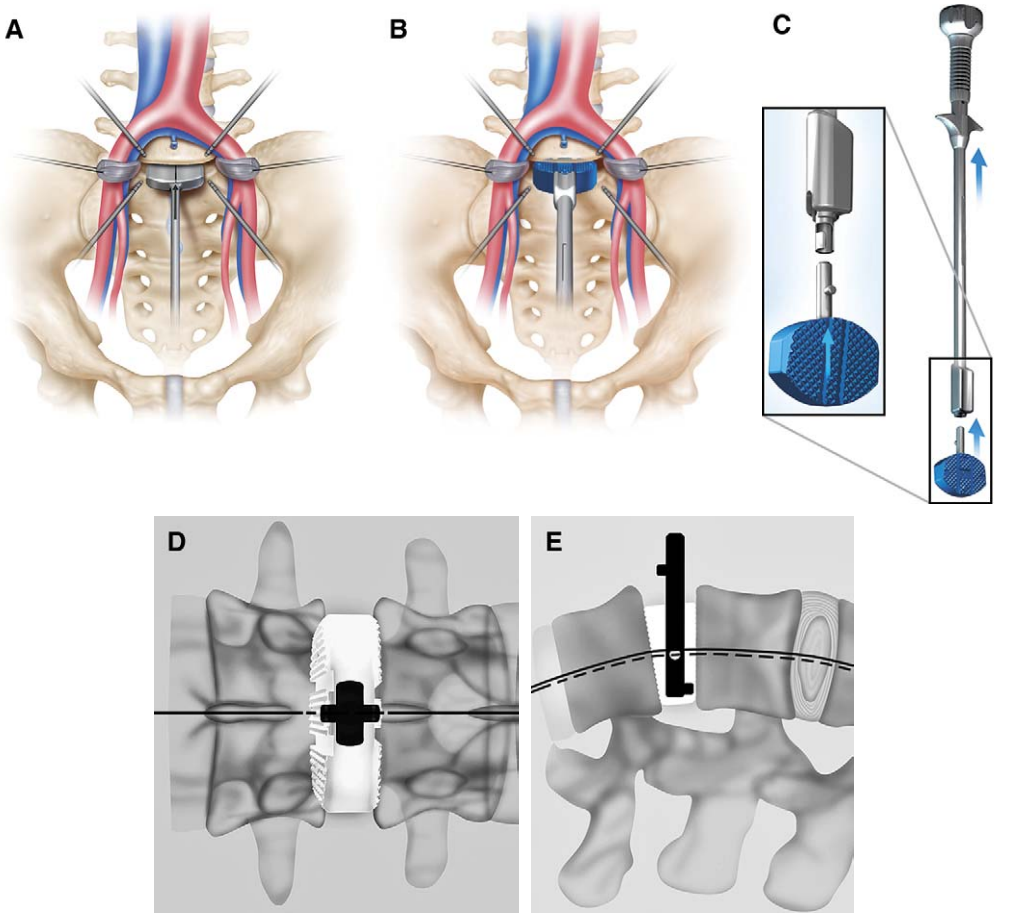

Fig. 8. (*A–E*) Implantation trialing.

- It may be necessary to increase lordosis in the operative segment to initiate impaction.
- It is important to use lateral fluoroscopy to monitor the depth of the pilot driver accurately.
- Place the patient in the neutral supine position when the pilot driver is halfway into position (Fig. 10).
- Use the slap hammer to remove the pilot driver from the disc space safely.

The use of the pilot driver is critical. The pilot drivers match the footprint geometry and closely approximate the height of the two end plates during implantation. Thus, if the pilot driver can be impacted to the desired location for the prosthesis, successful implantation of the end plates to that same location can be achieved. If this is not possible, additional discectomy or end plate preparation is required.

End plate insertion

- Attach the end plate insertion tips corresponding to the chosen end plate size to the spreading and insertion forceps.
- Load the selected end plates into the end plate insertion tips, placing the more angled of the two end plates inferiorly.
- When using an oblique end plate, load the thicker margin into the end plate insertion tip first. The thick margin must be placed ventrally within the vertebral disc space.
- Carefully position the spreading and insertion forceps, paying particular attention to the AP midline.
- Carefully insert the end plates into the disc space with the assistance of the guided impactor.

Fig. 9. (*A, B*) Midline identification.

- Monitor the insertion with fluoroscopy to control the posterior depth accurately and to verify the appropriate lordotic angle.
- If needed, increase lordosis to initiate impaction of the implant. Bring the table to the neutral supine position when the implant is halfway in the disc space.
- The final position of the center of the end plates should be 2 mm dorsal to the lateral midline of the vertebral body and centered on the medial/lateral midline (Fig. 11).

Core trial

- With the end plates now in place, open the disc space using the spreading and insertion forceps.
- Sequentially distract the disc space using the spacers and modular T-handle corresponding to the core heights. Care must be taken to avoid contact between the spacer and the "polished" articulating surface of the end plates. Therefore, a parallel orientation should be maintained between the shaft of the spacer and the spreading and insertion forceps.
- Once the appropriate distraction is achieved, the size indicated on the spacer can be used to select the appropriate core trial.
- Confirm the appropriate height of the sliding core by placing the core trials between the end plates.
- Slight resistance may be felt as the core trial is passed through the rims of the articulating surfaces of the end plates. Once the core trial is in position, it moves within the articulating surface of the end plates. The core trial should never be impacted (Fig. 12).
- If desired, the core trial can be inserted and the distraction force of the spreading and insertion forceps released so that the end plates close around the core trial, demonstrating the final position and height.

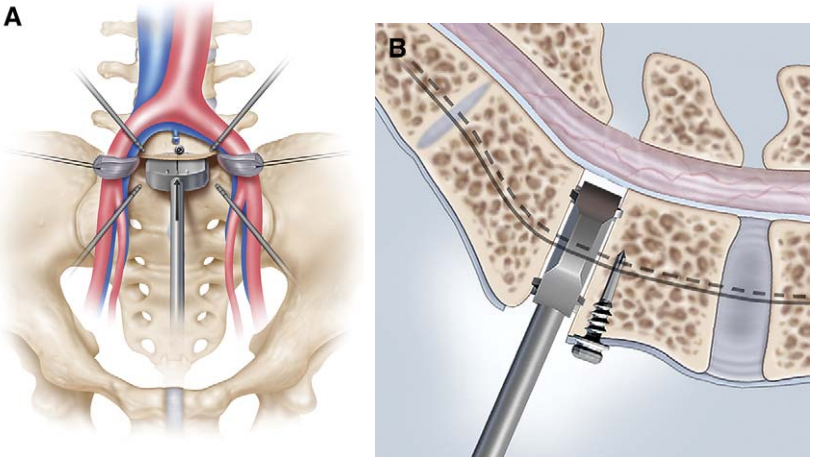

Fig. 10. (*A, B*) Confirming positioning.

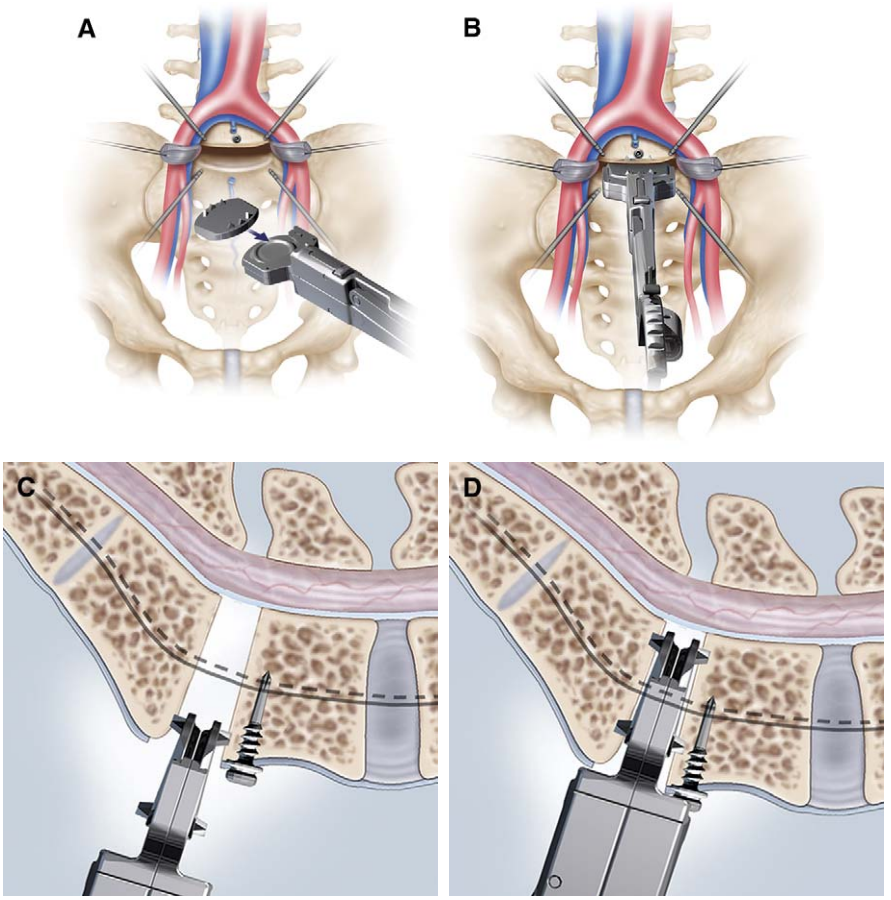

Fig. 11. (*A–D*) End plate insertion.

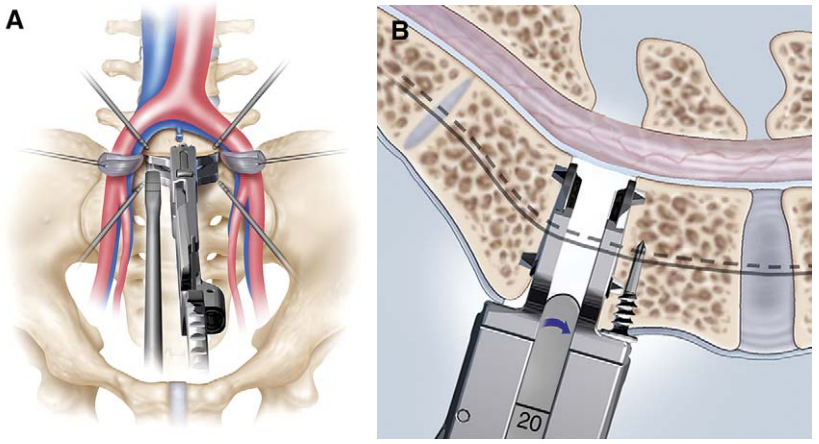

Fig. 12. (*A, B*) Core trial.

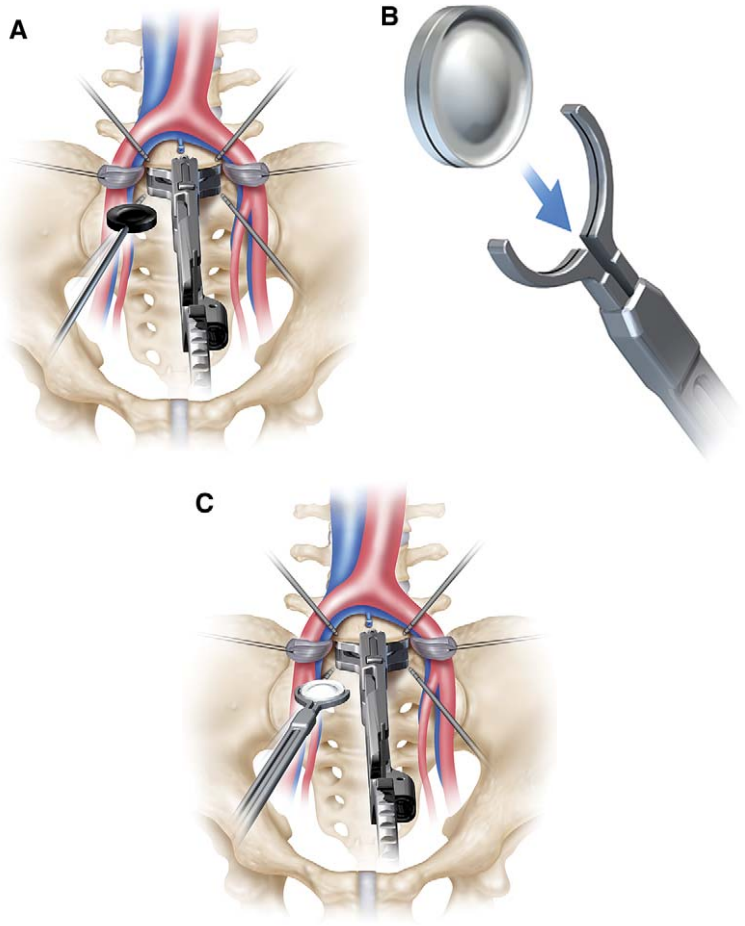

Fig. 13. (*A–C*) Core insertion and implantation.

- A lateral radiograph can be taken to show the height and lordotic angle of the prosthesis.

Core insertion

- Load the appropriate core insertion tip into the core insertion instrument.
- Load the sliding core into the core insertion tip by squeezing the handle.
- Insert the sliding core between the end plates. If resistance is felt, carefully increase the distraction.
- Release the distraction on the spreading and insertion forceps, allowing the end plates to close around and engage the sliding core.
- Release the sliding core by squeezing the handle of the core insertion instrument.
- Remove the core insertion instrument.
- Use the slap hammer to remove the spreading and insertion forceps safely (Fig. 13).

Final positioning

- Verify the final position of the Charité Artificial Disc using fluoroscopy. It is imperative that the prosthesis is in the correct position in the AP and lateral planes.
- If necessary, the position of the prosthesis can be altered slightly using the appropriately sized grooved driver.
- The Charité Artificial Disc may be repositioned during surgery in the event of gross malpositioning. The entire prosthesis can be removed and reimplanted by carefully distracting the interbody space, removing the

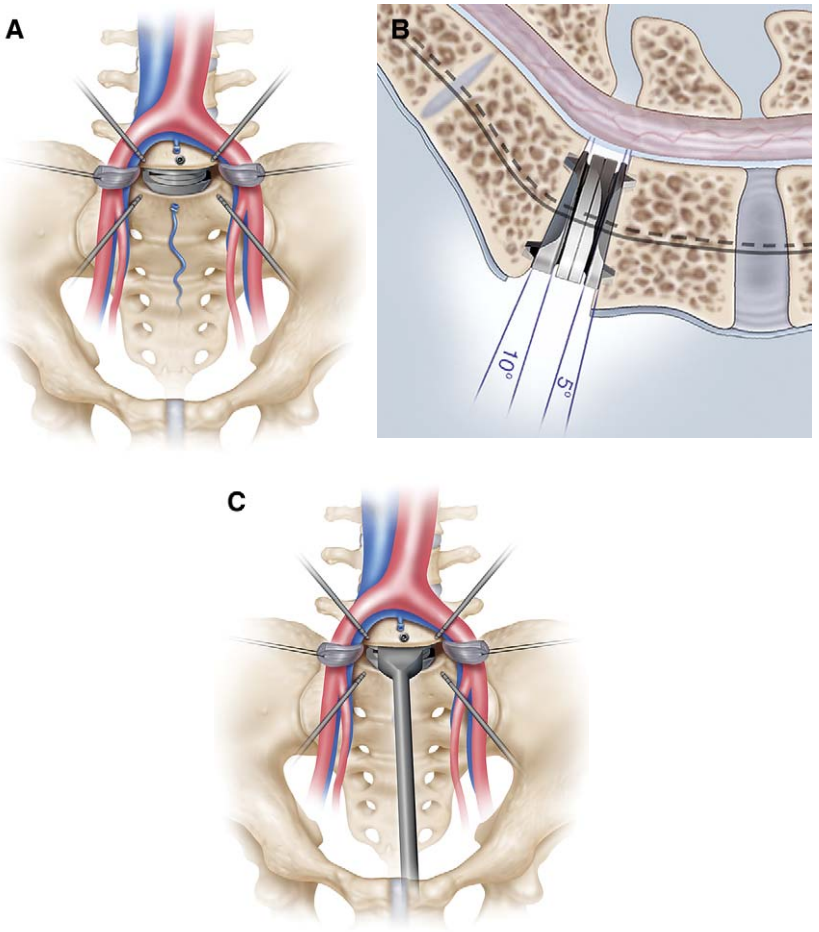

Fig. 14. (*A–C*) Final positioning.

sliding core, and then removing each end plate one at a time.

- Care must be taken not to damage the sliding core and the polished surfaces of the end plates.
- Once the final position has been confirmed, the single end plate impactor may be used manually to engage the ventral fixation teeth of the end plates into the vertebral body, thus providing additional initial fixation (Fig. 14).

Closing

- The midline marker must be removed before closing (Fig. 15).
- If desired, suture the annulus around the disc space. Remove the retractor pins in reverse

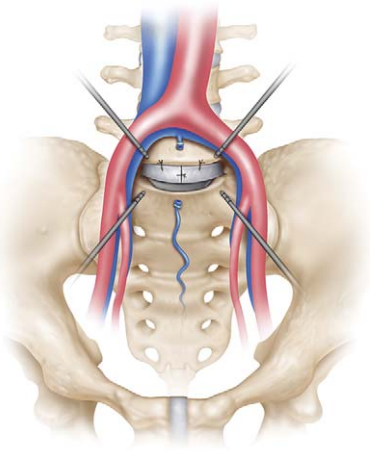

Fig. 15. Closing.

order to that in which they were implanted, with care being taken to protect the vasculature as they are removed.

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