Total Disc Arthroplasty

51

Benjamin Ebben and Miranda Bice

Contents

Abstract

The concept of total disc replacement in the spine has been present for decades because of the desire to maintain physiologic motion of spinal segments while treating underlying pain-generating pathology. There has been considerable evolution of this technology,

B. Ebben
University of Wisconsin, Madison, WI, USA
e-mail: bebben@uwhealth.org; bebben@wisc.edu

M. Bice (✉)
University of Wisconsin School of Medicine and Public Health, Madison, WI, USA
e-mail: bice@ortho.wisc.edu

B. C. Cheng (ed.), *Handbook of Spine Technology*,
https://doi.org/10.1007/978-3-319-44424-6_58

with successes, failures, and the popularity of these procedures waxing and waning over time. Much in vitro and in vivo research has been done on both past and current devices to facilitate understanding of this technology and optimize utilization for clinical success and progress. This chapter describes some of the historical background, current uses and approved devices, surgical techniques, complications, revision options, and outcomes of both lumbar and cervical disc replacement.

Keywords

Lumbar disc replacement · Cervical disc replacement · Disc arthroplasty · Adjacent segment degeneration · Adjacent segment disease · Motion sparing · Spine arthroplasty · Artificial disc

Introduction

Historically, the initial management of painful degenerative spinal disc disease has been conservative and supportive measures. When these efforts fail to provide meaningful relief, decompression and arthrodesis is generally considered the accepted surgical intervention for its effectiveness in maintaining intervertebral height, establishing segmental stability, and improving pain. Overall, arthrodesis has proven quite successful over time. However, the reported reoperation rates cannot be ignored. These reoperations are frequently reported due to persistent or recurrent pain from symptomatic adjacent level degeneration or pseudarthrosis. Although heavily debated, current thought suggests that the complications associated with arthrodesis, namely, adjacent level disease, exist secondary to the alteration of normal spine biomechanics associated with the fusion of a previously mobile segment. There has been a considerable amount of literature dedicated to not only uncovering the presumed association between arthrodesis and adjacent level deterioration but also to investigating the biomechanical and biochemical basis behind this theoretical relationship.

In vitro cadaveric studies have demonstrated increased stresses at mobile segments adjacent to the site of fusion in the cervical spine. Eck et al. found that intradiscal pressure (IDP) increased significantly both cranial and caudal to a cervical fusion during flexion compared to an intact spine by 73% and 45%, respectively (Eck et al. 2002). Similarly, Chang and colleagues reported significantly elevated IDP in the cranial mobile segment during both flexion and extension following cervical fusion. These investigators also demonstrated effects on posterior element stress levels following cervical fusion and found that facet joint forces were significantly greater at both adjacent mobile segments during extension (Chang et al. 2007). A similar group of cadaveric biomechanical studies have been performed in the lumbar spine following instrumented arthrodesis with comparable findings of increased stress within the intervertebral discs and/or facet joints (Cunningham et al. 1997; Lee and Langrana 1984). Examination of intervertebral disc physiology shows that the health of this avascular structure is related to the relative concentrations of specific collagen and proteoglycan subtypes. The maintenance of this extracellular matrix is, in turn, reliant upon adequate diffusion of nutrients through the vertebral body cartilaginous endplate. It can be reasonably inferred that the discs within adjacent mobile segments exposed to chronically elevated intradiscal hydrostatic pressures following spinal arthrodesis may degenerate at an accelerated rate due to the disruption of this intricate metabolic balance (Buckwalter 1995; Hutton et al. 1998).

Long-term radiologic follow-up studies after spinal fusion have reported high incidences of adjacent level degenerative changes. In 2004, Goffin et al. published their radiologic findings for a series of 180 patients an average of 8 years following cervical interbody fusion. They found that 92% of the patients demonstrated an increase in degeneration score at adjacent levels at long-term follow-up. A suggestive trend of correlation, albeit not statistically significant, was appreciated between adjacent level radiologic degeneration and clinical outcomes (Goffin et al. 2004). Other authors have tried correlating these observed

radiologic changes with clinical outcomes. In a landmark study, Hilibrand and colleagues studied the development of new radiculopathy or myelopathy referable to mobile segments adjacent to previous anterior cervical arthrodesis in 374 patients available for 10-year follow-up. They reported a nearly 3% annual incidence of symptomatic adjacent segment degeneration and a Kaplan-Meier survival analysis predicted an overall prevalence of 25.6% within the first 10 years after the procedure. Twenty-seven patients underwent a second operation for fusion at the adjacent symptomatic level (Hilibrand et al. 1999). Ghiselli et al. studied adjacent segment disease in the lumbar spine and reported similar clinical outcomes. Fifty-nine of 215 patients, followed for an average of 6.7 years after posterior lumbar arthrodesis, developed symptomatic adjacent segment degeneration that warranted additional surgery. The authors reported a nearly 4% annual incidence of surgical intervention for adjacent segment disease and their survivorship analysis predicted that 36.1% of patients would have new disease requiring reoperation within the first 10 years following the index procedure (Ghiselli et al. 2004). There is a sizeable amount of literature further investigating clinical outcomes following spinal arthrodesis with a focus on defining its contribution to the development of symptomatic adjacent segment degeneration (Park et al. 2004; Gore and Sepic 1998).

Despite the substantial supporting data, no causation has been definitively proven. Randomized controlled trials investigating the relative rates of symptomatic adjacent segment disease with and without arthrodesis do not exist as it would be unethical to deny patients a fusion operation for a situation in which they would otherwise be indicated. Some experts would argue that adjacent segment degeneration is a consequence of natural history and can be expected as an inherent fate in a spine that has already shown signs of degenerative disease. To this end, studies have attempted to decipher the relative contributions of fusion and the natural aging process. Matsumoto et al. evaluated the pre-surgery and 10-year follow-up MRI images of 64 patients who underwent anterior cervical decompression and fusion (ACDF). They compared the observed radiologic changes to a group of asymptomatic volunteers who, likewise, underwent a baseline and 10-year follow-up MRI. The incidence of progression of degenerative disc disease was significantly higher in the ACDF group (Matsumoto et al. 2010). Nonetheless, this study was limited by differences in group characteristics including both a higher mean age and observed frequency of baseline MRI degenerative findings in the ACDF group. Interestingly, two of the landmark publications referenced earlier found that multilevel fusion is actually protective rather than promotive when it comes to adjacent segment degeneration. Hilibrand et al. discovered that only 12% of patients who underwent multilevel arthrodesis developed symptomatic adjacent segment degeneration, an odds ratio of 0.64 when compared to single level (Hilibrand et al. 1999). In the lumbar spine, mobile segments adjacent to single-level arthrodesis were three times more likely to develop symptomatic adjacent segment degeneration than segments adjacent to a multilevel arthrodesis (Ghiselli et al. 2004).

Another frequently studied complication of spine arthrodesis is the development of a symptomatic pseudarthrosis. There are established but quite variable rates of pseudarthrosis within the cervical and lumbar spine literature. Rates are technique-dependent and vary based on multiple factors including the use of an interbody device, fixation rigidity, whether or not instrumentation was performed, choice of graft, etc. Martin and colleagues used a registry of statewide (Washington) hospital discharges to investigate rates of reoperation following lumbar spinal surgery and found that the cumulative 11-year incidence of reoperation following an index fusion procedure was 20%. Of the 471 reoperations following an index fusion, 23.6% were associated with a coding of pseudarthrosis (Martin et al. 2007). A 47-article meta-analysis conducted to determine success and complication rates for lumbar spinal fusion found pseudarthrosis as the most frequently reported complication (14%). Authors also noted a positive relationship between satisfactory patient outcomes and achievement of solid

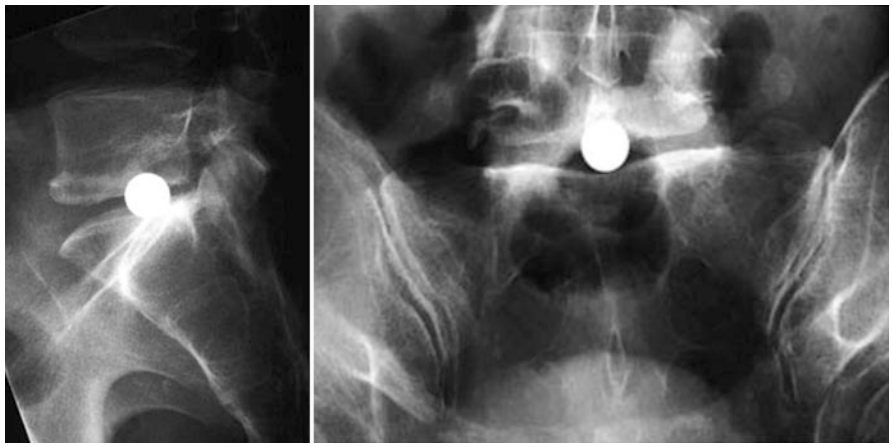

Fig. 1 Fernstrom Ball prosthesis. (Reprinted with permission from Szpalski et al. *Eur Spine J* 2002)

arthrodesis (Turner et al. 1992). A similar meta-analysis investigating the overall incidence of pseudarthrosis following fusion in the cervical spine found a much lower overall rate of 2.6% (Shriver et al. 2015). The true incidence of spine pseudarthrosis is probably underestimated as a percentage are asymptomatic and prompt no further diagnostic workup or additional management.

To combat the pitfalls discussed above that are associated with spinal fusion, the field of spinal arthroplasty and the concept of motion sparing spinal implants evolved. The growth of this field was heavily influenced by the technologic successes of motion-preserving joint prostheses for the treatment of degenerative joint disease in the hip and knee. Motion sparing technology could potentially circumvent the limitations of arthrodesis. In theory, by implanting a motion sparing prosthetic within the intervertebral space, accelerated adjacent segment degeneration could be mitigated. The potential for pseudarthrosis development could be eliminated with no attempt at surgical fusion. In addition, maintaining the mobility of the spinal segment could lead to preservation of normal spine biomechanics and could maximize patient motion, function, and improve clinical outcomes. Along these lines, investigators began to define the characteristics of an ideal spinal arthroplasty system which would include the reproduction of native disc viscoelastic properties, the reproduction of native disc motion characteristics, and the ability to withstand the mechanical and chemical environment of the intervertebral space.

A Swedish surgeon, Ulf Fernström, is historically credited with implantation of the first artificial disc in a human patient, and his experiences were published in the late 1960s and the early 1970s. His prosthesis was quite simple and consisted of a single, corrosion-resistant stainless steel ball bearing implanted into the center of the intervertebral disc space (Fig. 1). It is estimated that he implanted approximately 250 of these devices in total, both in the lumbar and cervical spine (Le et al. 2004; Basho and Hood 2012; Baaj et al. 2009). A duo of South African surgeons, impressed with Fernström's early results, also implanted 75 of these devices in the cervical spine during the same time period, for the treatment of intractable headache and cervico-brachialgia (Reitz and Joubert 1964). Ultimately, with longer-term follow-up, these mobile bearings failed miserably. The unconstrained nature created segmental spinal hypermobility, and the lack of endplate support resulted in a tendency for subsidence and migration into the superior endplate (Le et al. 2004). These early disappointments lead to a temporary abandonment of spinal arthroplasty surgical practice in favor of arthrodesis until the 1980s. Nonetheless, Fernström was ahead of his time in recognizing the potential benefits of motion sparing devices, and other researchers continued to investigate alternative designs.

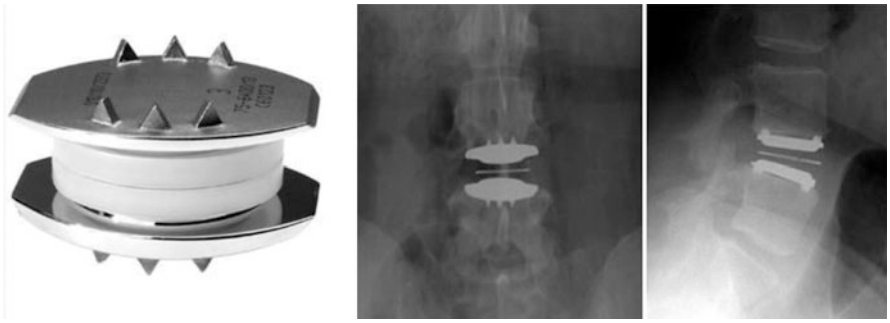

Fig. 2 Charite III prosthesis. (Reprinted with permission from Atkins, et al. *Lumbar Disc Arthroplasty.* In: Essentials of Spinal Stabilization. Holly L., Anderson P. (eds). Springer, Cham. 2017)

Multiple spine arthroplasty models were subsequently developed during the second half of the twentieth century, a majority of which were patented or published but never reached the stage of human implantation (Szpalski et al. 2002).

Spine arthroplasty then garnered renewed interest in 1984 after the maiden implantation of the German-engineered SB Charité I prosthesis, which was the first approved and commercially available lumbar total disc replacement system available in Europe (Link 2002). The SB Charité I was an unconstrained device featuring small, circular, polished steel alloy endplates with anchoring teeth for cementless fixation and a sliding ultrahigh molecular weight polyethylene (UHMWPE) core marked with a radio-opaque circumferential wire (Büttner-Janz et al. 1989). The sliding core allowed for a dynamic instantaneous axis of rotation that could translate during flexion and extension, more closely mimicking normal lumbar spinal motion (Bono and Garfin 2004). Similar to Fernström's ball bearing implants, the earliest SB Charité model lacked sufficient endplate contact surface area secondary to its undersized metal endplates and was noted to subside or migrate axially (Link 2002). This design flaw prompted development of a second version, the SB Charité II, with enlarged metal endplates. Problems with fatigue fractures ultimately lead to the third- and final generation Link SB Charité III (DePuy) device which started production in 1987 in Europe and eventually received FDA approval in the United States in 2004 after 2-year follow-up results from its investigational device exemption (IDE) randomized controlled trial showed noninferiority to lumbar arthrodesis (Fig. 2) (Blumenthal et al. 2005). Subsequent 5-year follow-up data showed a FDA-defined clinical success rate of 58% in the Charité group and 51% in the arthrodesis group (Guyer et al. 2009). Even longer-term follow-up and device retrieval studies have become increasingly available and shed light onto some of the device late failure mechanisms. Punt et al. published a case series analyzing late complications following SB Charité III disc implantation in a group of 75 unsatisfied patients that presented to their institution with persistent leg and back pain. Forty-six of the 75 patients ultimately ended up undergoing a salvage operation, and the authors were directly involved in 37 of these cases. They reported implant subsidence, adjacent disc degeneration, and index-level facet arthrosis as the three most common late complications. Of the 39 cases of observed implant subsidence, they estimated that 24 were secondary to an undersized prosthesis. The authors also reported on 8 cases of anterior-posterior migration and 10 cases of polyethylene core wire breakage (Punt et al. 2007). Van Ooij and colleagues reported very similar findings in their 27 patient case series (van Ooij et al. 2003). In a 2007 international multicenter retrieval study of 21 explanted SB Charité III implants from patients undergoing revision surgery due to persistent pain, Kurtz et al. analyzed polyethylene wear patterns and found the peripheral rim to be susceptible to pinching as evidenced by the observation of plastic

deformation, fracture, cracking, and other fatigue damage in most of the specimens (Kurtz et al. 2007). Current long-term clinical outcome data and the results of the most recent FDA IDE randomized controlled trials for the SB Charité III, its contemporaries, and its successors will be covered elsewhere in this chapter. Overall, however, the SB Charité III was quite successful and underwent widespread implantation for many years. It was removed from the US market in 2013 as part of a business decision when DePuy purchased Synthes and elected to sell its lumbar arthroplasty system, the ProDisc-L.

Currently, there are two FDA-approved lumbar arthroplasty systems. The Synthes ProDisc-L was developed concurrently with the SB Charité III in the late 1980s. Like the Charité, it underwent stepwise modifications from its initial design to the release of the current model, which received FDA approval in 2006. Unlike the Charité, the ProDisc-L is a semiconstrained device. There is a single articulating interface between a polyethylene bearing and the superior endplate. The polyethylene bearing is fixed to the inferior endplate and does not slide or translate as in the Charité. The ProDisc-L is secured to the neighboring vertebral bodies via a keel or midline sagittal fin (Bono and Garfin 2004). There is currently a considerable amount of longer-term follow-up studies (>5 years) supporting the use of this device in patients with lumbar degenerative disc disease. The ActivL (Aesculap Implant Systems) prosthesis received FDA approval in 2015 after its 2-year follow-up data showed noninferiority to the other two previously mentioned lumbar arthroplasty prostheses. This implant has been marketed as next generation in that it is designed to be inserted as a single unit, obviating the need for multiple spinal distractions. In addition, its polyethylene inlay is affixed to the inferior endplate in a way that permits a limited amount of translational motion (Garcia et al. 2015).

The technological triumphs in lumbar arthroplasty motivated the pursuit for a counterpart in the cervical spine. The first modern era artificial cervical disc was developed in the United Kingdom and was implanted in 1991. This device came to be known as the Cummins-Bristol and had two distinctive design features when contrasted to the previously discussed lumbar prosthetics: (1) a metal-on-metal articulation with no separate intercalary polyethylene bearing and (2) anterior flanges for the purpose of obtaining immediate anchoring screw fixation into the cranial and caudal vertebral bodies. Early results were quite poor and related to failure of the anterior screw fixation via screw pullout and screw fracture. Following modifications to screw hole positions and the addition of locking screw capabilities, a subsequent group of 20 patients, implanted with the device between 1991 and 1996, fared much better according to Cummins and colleagues. The authors reported that 75% of the patients experienced an improvement in preoperative symptoms and that 88% of the patients available for follow-up in 1996 had radiographic evidence of maintenance of index level motion (Le et al. 2004; Cummins et al. 1998). There were also four patients with persistent dysphagia attributed to the high profile of the anterior flanges. Two years later, a redesigned second-generation version of the Cummins-Bristol artificial disc, known as the Frenchay, was implanted into 15 patients as part of a pilot study (Fig. 3). The Frenchay's superior component "ball" remained hemispherical, while the inferior component "socket" was shallow and ellipsoid making for an incongruent articulation. Theoretically, this permitted the cranial vertebral body to passively align with the dynamic center axis of rotation as dictated by the facet joints. At 2 years, the prosthetic joints remained mobile with an average arc of 6.5° in flexion and extension, there were no cases of joint subluxation or subsidence, and there were 3 reoperations, only one of which involved explanation of the prosthesis for looseness (Wigfield et al. 2002). The Frenchay would eventually become the Prestige (Medtronic), which is one of the commercially available cervical total disc replacement systems on the market today. This device received US FDA approval in 2007, and the latest long-term (7-year) clinical outcome data has been very favorable showing a statistically significant greater overall success rate of 75% in the

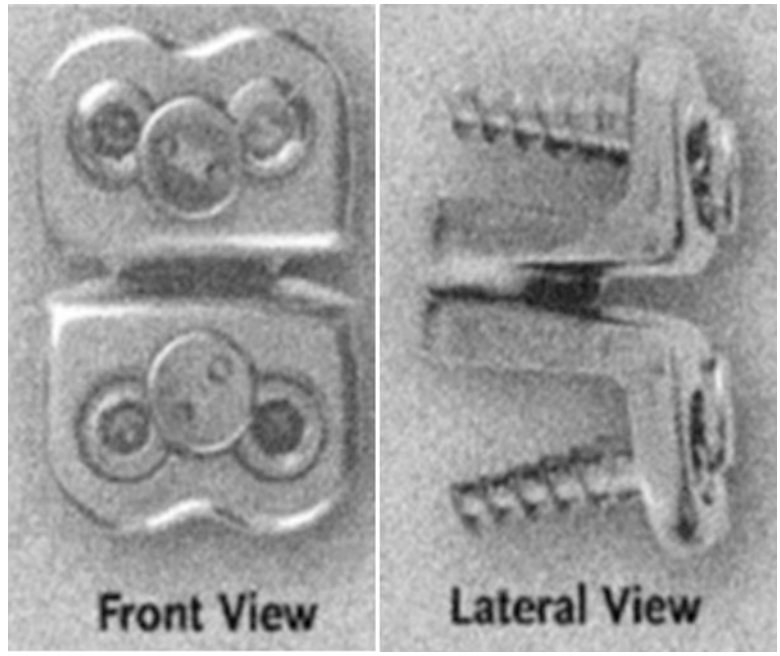

Fig. 3 Frenchay prosthesis. (Reprinted with permission from Buell, et al. Cervical Arthroplasty: Long-Term Outcomes. In: Handbook of Spine Technology. Cheng B. (eds). Springer, Cham. 2019)

arthroplasty group compared to 64% in the control arthrodesis group. These authors also reported maintenance of physiologic segmental angular motion at the index level and an index level secondary surgery 11-year cumulative rate of 4.8% compared to 13.7% in the arthrodesis group (Burkus et al. 2014).

Another unique, albeit unsuccessful, cervical arthroplasty concept is worthy of brief mention. The Pointillart cervical prosthetic entered the scene momentarily between 1998 and 1999, and its concept was influenced by unipolar hip replacement designs (Fig. 4). It featured a single titanium base piece which was anchored via screws into the caudal vertebral body and a carbon sliding cranial surface meant to articulate with the inferior endplate of the cranial vertebral body. The inventing surgeon implanted this device into ten patients and reported "total failure" after 1-year follow-up radiographs showed spontaneous fusion and resultant absence of motion across the index level in eight of the patients (Pointillart 2001).

There are currently six FDA-approved cervical total disc replacement systems: Prestige (Medtronic), Bryan (Medtronic), Mobi-C (Zimmer-Biomet), ProDisc-C (DePuy Synthes), PCM (NuVasive), and Secure-C (Globus Medical). All of these devices have 2–7-year US FDA IDE prospective randomized controlled trial clinical outcome data showing non-inferiority to anterior cervical decompression and fusion (Sasso et al. 2011; Hisey et al. 2016; Janssen et al. 2015; Phillips et al. 2015; Vaccaro et al. 2013). As with any surgical procedure, particularly in the spine, strict adherence to appropriate criteria of both patient selection and surgical indications is paramount for successful outcomes.

Surgical Techniques: Cervical Disc Replacement

Indications

- Subaxial spinal motion segments between C3 and C7
- One or two-level pathology
- Radiculopathy and/or myelopathy secondary to neural element compression by:
  - Soft disc herniation
  - Osteophyte formation

Fig. 4 Pointillart prosthesis. (Reproduced with permission from Pointillart, *Spine* 2001)

Contraindications

- Spondylolisthesis, instability with translation of greater than 3.5 mm
- Deformity
  - Including kyphosis of greater than 11° at the target level
- Trauma (concern for disruption or irregularity of vertebral endplates)
- Prior cervical laminectomy (concern for disruption of posterior stabilizing elements at the level of interest)
- Prior surgery at the level of interest
- Osteoporosis (T-score less than −2.5)
- Other metabolic bone diseases which may result in abnormal bony architecture and/or stability
  - Rheumatoid arthritis, other inflammatory arthropathies
  - Renal disease
  - Cancer
  - Long-term steroid use
- Infection
- Severe facet arthropathy
- Ankylosing disorders
  - Ankylosing spondylitis
  - Diffuse idiopathic skeletal hyperostosis (DISH)
  - Ossification of the posterior longitudinal ligament (OPLL)
- Metal allergy
- Isolated axial neck pain without radiculopathy or myelopathy

Relevant Anatomy

A standard Smith-Robinson approach to the anterior cervical spine is utilized for cervical disc replacement. While this is generally regarded as a common and safe approach, detailed knowledge and understanding of the local anatomy is necessary to minimize inadvertent injury to several important structures:

Nerves

- **Superior laryngeal nerve** is typically encountered for procedures in the upper cervical spine, at or above C3 and C4. It can be identified traversing from the carotid sheath to the larynx at the thyrohyoid membrane along with the superior laryngeal artery. As this nerve contributes to control of a vocal cords, injury to it may result in difficulty with voice control (dysphonia) and swallowing or aspiration (dysphagia).
- **Recurrent laryngeal nerve** is occasionally visualized on its recurrent path in the tracheoesophageal groove. On the left, once the nerve exits the carotid sheath, it

courses inferiorly under the aortic arch prior to returning cephalad in the tracheoesophageal groove. The recurrent laryngeal nerve on the right is beneath the right subclavian artery and is less constant. For this reason, it is sometimes dogmatically believed to be safer to perform the approach on the left side as this course was previously felt to be more predictable; however this has not been demonstrated clinically, and there are many surgeons that perform this approach on the right side without any increased complication rate related to phonation or swallowing. This nerve also contributes to control of vocal cords well as all of the laryngeal muscles and the esophagus. Similar to injury of the superior laryngeal nerve, injury to this nerve can also result in difficulties with dysphonia and or dysphagia.

- **Sympathetic chain** lies on the ventral surface of the longus coli muscles. Because of this, manipulation in this area is generally avoided, with dissection generally limited to the medial aspect of the longus coli. Injury to the sympathetic chain can result in an ipsilateral Horner's syndrome.

Vessels

- **External jugular vein** lies between the platysma and the caudal mastoid. It often is lateral to the operative field; however occasionally the main external jugular or large branches of it can cross the surgical field. Injury to it may not result in significant functional impairment; however it can bleed quite vigorously, adding difficulty and time to the surgery.
- **Carotid artery** travels within the carotid sheath. It can be easily palpated as a pencil-like structure deep to the sternocleidomastoid muscle belly and used as a landmark for the approach as the entirety of the approach should be medial to this structure along with the other contents of the carotid sheath.
- **Vertebral artery** travels within the foramen transversarium of the cervical vertebrae. It typically enters at C6, although can also enter at C7, and travels proximally to supply the brainstem and posterior cranial contents. The longus colli muscle lies ventral to the transverse foramen containing these vessels, and so dissection deep to the longus muscle belly is very limited and cautious to avoid injury to the vertebral arteries. However, should a vertebral artery injury occur elsewhere during the procedure, dissection deep to the longus colli can be utilized to gain access to the vessel and control bleeding. Injury to this blood vessel can result in rapid exsanguination. The overall implications of vertebral artery injury varies widely, from asymptomatic to stroke or even death.

Trachea and Esophagus are midline structures medial to the plane of approach. Further mobilization is often necessary for adequate exposure to the targeted disc site(s). Because of its cartilaginous rings, the trachea is more easily identified. The esophagus lies deep to the trachea. As it is composed of smooth muscle of varying degrees of thickness, it is more prone to inadvertent injury during anterior cervical approaches. Injuries to these structures are often occult and not always identified intraoperatively but can lead to profound morbidity and even mortality if not identified and treated appropriately. For these reasons, a high index of suspicion is mandatory during both the index procedure and follow-up if anything is amiss.

Positioning and Approach

The patient is positioned supine on a radiolucent operating table. The authors prefer to have the patient as caudal on the table as patient's height will allow to provide space for the C-arm rostral to the patient when not in use. The neck is positioned in neutral alignment. The arthroplasty devices are not intended to correct or change alignment, and so native alignment is maintained during positioning so as to avoid improper implant placement. If the shoulders preclude adequate visualization of the targeted surgical level, gentle traction can be gained by either taping the shoulders down caudally to the table or placing wraps about the wrists

that can then be utilized for intermittent traction. If continuous traction is utilized, the surgeon must ensure that excessive traction is not sustained on the brachial plexus for the entirety of the procedure to decrease the chance of root palsies.

A standard Smith-Robinson approach is performed. This is often a left-sided approach, although can be performed on either side depending on surgeon preference. The location of the incision is planned over the targeted disc space based on manual palpation of landmarks and/or fluoroscopy. If possible, the incision is placed within a natural skin crease for cosmesis. Prior to incision, it can be helpful to mark the sternal notch to facilitate orientation to the midline throughout the procedure, as precise alignment is of utmost importance for accurate placement of arthroplasty implants. A 2–3 cm transverse incision is made, extending approximately from midline to the medial border of the sternocleidomastoid muscle. Subcutaneous fat and platysma are then divided. The superficial layer of the deep cervical fascia is divided in the plane visualized between the sternocleidomastoid laterally and the strap muscles medially. The omohyoid can be sacrificed if needed to gain access to the lower cervical levels. Continued blunt dissection in this plane will then lead to the spine, with the carotid sheath the laterally and the larynx and esophagus medially. When the spine is encountered following this plane, a snap is placed on the annulus of the intended surgical level, and localization is confirmed using lateral cross-table fluoroscopy. Adjacent to the target disc level, the longus colli are gently elevated bilaterally to allow adequate access to the disc space out to the uncovertebral joints, however taking care not to dissect too far laterally as the anterior aspect of the vertebral body slopes down and away from the ventral surface to avoid injury to the vertebral arteries. At this point, self-retaining radiolucent retractors can be placed deep to the elevated longus flaps. The annulotomy is performed followed by the discectomy portion of the procedure.

Implant-Specific Instrumentation

Prestige LP (Medtronic Sofamor Danek) (Prestige LP 2009) (Fig. 5)

- *Device type:*
  - Metal-on-metal (titanium alloy)
  - Ball and socket
- *Procedure*

  Caspar pins are placed in the rostral and caudal vertebral bodies, taking care to ensure that placement is midline, parallel to the endplates and with sufficient distance to prevent violation of the endplates during placement or disc space preparation, and parallel to one another so as not to introduce any kyphosis or lordosis during disc space preparation. Fluoroscopic guidance is highly

Fig. 5 Medtronic Prestige LP prosthesis. (Reproduced with permission from Nasto et al. *Cervical Disc Arthroplasty.* In: Cervical Spine. Menchetti P. (eds) Springer, Cham. 2016)

advised when placing these pins. The remainder of the decompression is completed using Kerrison, curettes, and a bur to facilitate complete osteophyte removal for a wide bilateral foraminal decompression. The posterior longitudinal ligament (PLL) is resected. The endplates are gently burred to provide a flat and parallel disc space; however care is taken to limit amount of cortical bone removed to minimize risk of subsidence. The rasp can facilitate fine-tuning of this step after burring. The anterior vertebral bodies are also flattened with the bur so that to the flanges of the prosthesis will lie flush to the anterior aspect of the vertebral body. Periosteum present on the adjacent vertebral bodies is removed with the monopolar cautery, and all bone dust is copiously irrigated and removed to decrease chance of heterotopic ossification formation. The trial is inserted, and sizing is confirmed using lateral fluoroscopy as well as manual assessment of the resistance encountered for insertion and removal. Ensure the tabs on the trial fit flush with the anterior vertebral body. Compare the trial size and space to adjacent healthy disc spaces and facet joints on fluoroscopy. At this point, the Trial Cutter Guide is placed into the prepared disc space. Confirm that the cutter guide is perfectly midline using fluoroscopy because all steps moving forward will now dictate the final positioning of the implant. The Rail Cutter Bit is then used to prepare the rail tracts; the guide is held in place between rail preps with the Temporary Fixation Pins. When all four rails have been cut, all instruments are removed from the disc space. The Rail Punch is tapped into the disc space to complete the rail preparation. The prosthesis is then implanted into the prepared disc space, with the ball endplate rostral. Bone wax can then be applied over the exposed anterior aspect of the implant and over the exposed vertebral bodies to minimize heterotopic ossification. Ensure that the prosthesis remains parallel and the inserter perpendicular to the prepared disc space. Lateral fluoroscopy is used to guide depth of placement, and AP views confirm accurate coronal positioning.

Mobi-C (Zimmer Biomet) (Mobi-C 2016) (Fig. 6)

- *Device type:*
  - Metal on plastic (ultrahigh molecular weight polyethylene)
  - Semiconstrained
- *Procedure*

  Caspar pins are placed in the rostral and caudal vertebral bodies, taking care to ensure that placement is midline, parallel to the endplates and with sufficient distance (5 mm) to prevent violation of the endplates during placement or disc space preparation, and parallel to one another so as not to introduce any kyphosis or lordosis during disc space preparation. The Intervertebral Distractor Device is used to distract the vertebral bodies, and then the distraction is maintained through the Caspar distractor pins. The recommended method of the remainder of the decompression for this device by the manufacture is without

Fig. 6 Mobi-C prosthesis. (Reprinted with permission from Buell, et al. Cervical Arthroplasty: Long-Term Outcomes. In: Handbook of Spine Technology. Cheng B. (eds). Springer, Cham. 2019)

the use of a burr to optimally preserved bony endplate integrity. Bilateral foraminotomies are performed with Kerrison. The PLL is resected to facilitate perpendicular disc space preparation and distraction. The inferior endplate is squared off as wide as possible within the corners of the uncus without complete removal of the uncinates to maximize the width of the footprint of the implant. Next, the Width Gauge is placed into the prepared disc space to determine the width and adequacy of endplate preparation. If this gauge does not lie flat on the endplate, then the uncinates are squared off further using curettes. The Paddle Distractor, Caspar pin, or depth gauge can be used to estimate the depth of the footprint. Do not include anterior osteophytes in this measurement to ensure accuracy of the anterior-posterior footprint measurement. Anterior osteophytes can be removed as needed to create a flat anterior surface; however do not remove the overhang of the superior endplate as this concavity is required to match the shape of the superior endplate of the implant. Place bone wax as needed on exposed or decorticated surfaces of the anterior vertebral body to decrease risk of heterotopic ossification formation. Placed the selected trial with slight distraction on the Caspar pins, and then release the distraction to confirm fit both manually assessing resistances as well as on AP and lateral fluoroscopy. Re-distract the Caspar pins, remove the trial, and place the pre-assembled implant into the prepared disc space, avoiding any rotation during implantation. This can be confirmed using lateral fluoroscopy, ensuring that the Alignment Tabs on the inferior plate remain in line with one another such that only one line is visible without obliquity. The inserter and PEEK cartridge are removed. The implant position can be fine-tuned with the plate impactor and tamp. Prior to removal of the, gently compress through them to seat the prosthesis teeth into the endplates. The Caspar pins are removed and bone wax placed within the defects to control bleeding. Final positioning is confirmed using AP and lateral fluoroscopy.

Bryan Disc (Medtronic Sofamor Danek) (Bryan 2005) (Fig. 7)

- *Device type:*
  - Metal on plastic (soft polyurethane core)
  - Semiconstrained
- *Procedure*

  The remainder of the discectomy is performed with hand instruments, taking care not to remove the uncinates to preserve reference anatomy. The overhanging lip of the anterior superior vertebral body is removed, and the anterior vertebral bodies are smoothed to create a flat surface. The Transverse Centering

Fig. 7 Bryan Disc prosthesis. (Reprinted with permission from Buell, et al. Cervical Arthroplasty: Long-Term Outcomes. In: Handbook of Spine Technology. Cheng B. (eds). Springer, Cham. 2019)

Tool and Centering Level are used to identify and mark the center of the superior vertebral body. This can be confirmed with fluoroscopy if needed. Use the Intradiscal Distractor to distract the disc space to 8.5 mm and maintain this for 60 s to stretch the ligaments. Select the appropriate Alignment Guide, attached it to the Milling Guide, and place it into the prepared disc space over a Steinmann pin which has been placed at the reference point previously marked by the Centering Tool. Place the Stabilizer with the Centering Level on the Alignment Guide. Confirm that the alignment Visualization Slots are parallel to and centered between the endplates using fluoroscopy. The drill pilot holes, place Anchor Posts, distract the disc space, and complete a thorough decompression. Prepare the endplates using provided rasps up to 8.5 mm. Mill the superior and inferior endplates with the included Milling Assembly. Fill the implant with sterile saline. Place the implant into the prepared disc space. Irrigate copiously and place bone wax into screw holes and on exposed cortical surfaces to decrease chance of heterotopic ossification formation. Confirm final placement on lateral and AP fluoroscopy.

Postoperative Protocol

Amount of activity as well as the use of a hard or soft collar is at the discretion of the surgeon. A course of nonsteroidal anti-inflammatories is often utilized to decrease heterotopic ossification. The type, amount, and duration are variable, although a 2-week course is common.

Complications

Adverse events related to the approach such as dysphagia, dysphonia, vascular, or tracheoesophageal injury are possible, but reported rates are not significantly different compared to standard anterior cervical discectomy and fusion procedures (Mummaneni et al. 2007). There are, however, complications unique to total disc arthroplasty. While the goal of cervical disc replacement is maintenance of motion to theoretically protect adjacent levels, heterotopic ossification at these levels of preserve motion has been reported. The rates of heterotopic ossification development very widely; however it is felt to infrequently negatively impact range of motion or postoperative outcome (Lee et al. 2010; Chen et al. 2011). Leung reported 17% incidence of heterotopic ossification with the Bryan total disc arthroplasty device as assessed with radiographs. About 11% of these patients had significant loss of motion; however this was not correlated to clinical outcome such as pain or function (Leung et al. 2005). Similarly, Tu assessed the presence of heterotopic ossification using CT. With this more sensitive method, it was detected in 50% of one- and two-level Bryan total disc arthroplasty recipients, but again without adverse effects on clinical outcomes (Tu et al. 2011). Copious irrigation throughout the procedure including endplate preparation as well as postoperative utilization of nonsteroidal anti-inflammatory medications is often recommended to minimize risk for heterotopic ossification formation.

Subsidence is another complication which is often suggested as a possibility; however it is not often demonstrated or reported in the literature (Hacker et al. 2013). Recommendations for avoidance of this complication are relative contraindication in osteoporotic patients, maximizing the footprint of the implant, avoidance of oversizing the disc space, and preserving the endplate integrity during disc space preparation.

Postoperative kyphosis has been observed following total disc arthroplasty. This is also felt to be multifactorial, with contributions such as excessive anterior superior endplate removal during endplate preparation, incorrect angle of insertion, and amount and direction of distraction during endplate preparation (Sears et al. 2007). Again, outcomes have been evaluated in the setting of postoperative kyphosis. Pickett demonstrated preserved range of motion and no significant difference in outcomes despite focal kyphosis, and overall cervical alignment was maintained (Pickett et al. 2004).

Vertebral body fractures are postulated to be a possible complication, particularly with the keeled implant either during insertion or postoperatively. This is potentially more relevant if multilevel keeled implants are placed, but reports are infrequent to date (Shim et al. 2007; Datta et al. 2007).

In an era of heightened awareness to bearing surface wear with resultant particulate debris and metallosis, this is certainly a concern for the majority of cervical disc replacement implant designs. There is, however, a paucity in the literature regarding clinical examples of this problem. In the cervical spine, Cavanaugh presented a case report of metal ion reactivity resulting in hypertrophic tissue formation posterior to the device and subsequent neural compression. This was addressed with removal of the implant, revision decompression, and anterior fusion with resolution of symptoms (Cavanaugh et al. 2009). More instances of bearing wear-related complications have been presented in the lumbar literature, although true incidence remains unknown (Kurtz et al. 2007; van Ooij et al. 2007; Hallab 2009).

Finally, persistent pain is always a concern following any surgical procedure intended to address pain. As related to cervical disc arthroplasty, ongoing radiculopathy is most often due to incomplete decompression, particularly in a motion sparing technique where osteophytes can progress if not completely removed at the time of the index procedure (Goffin et al. 2002).

Revision Options

While interest in cervical disc arthroplasty continues to grow, the extent of need for revision remains to be seen. There is a paucity in the literature regarding this topic at this time. In general, the revision procedure will largely depend on the underlying problem. Replacement of the device may be considered if the issue is positioning or inadequate decompression after the index procedure. If there is particulate reaction, revision may necessitate conversion to fusion. Corpectomy and anterior column reconstruction may be needed if there is excessive bone loss. Most surgical technique guides recommend simply separating the bone-implant interface with an osteotome or similar device and removing it in a manner similar to which it was placed for implant removal; however in practice this may not always be the case. In the author's experience, some painful cervical arthroplasty devices have been grossly loose and are easily removed during the revision procedure. If radiculopathy is felt to be from recurrent foraminal stenosis secondary to osteophyte formation, some others advocate for posterior foraminotomy to avoid a revision anterior procedure. Likewise, if the pathology dictates, posterior cervical fusion alone is also sometimes a consideration, again to avoid anterior reoperation.

Outcomes

Overall, anterior cervical disc arthroplasty seems to be favorable compared anterior cervical discectomy and fusion in both short- and medium-term studies for both one- and two-level disease (Sasso et al. 2011; Mummaneni et al. 2007; Heller et al. 2009; Murrey et al. 2009; Zou et al. 2017). There is some evidence that two-level cervical arthroplasty procedures may fare better than single-level procedures, perhaps by protection of levels that are already degenerating (Radcliff et al. 2017; Mehren et al. 2018; Sasso et al. 2017). With the technology being available for the better part of two decades at this point, longer-term data are continuing to show favorable outcomes. Some of these longer-term reports are smaller cohorts and without similar rigor as was reported in the original IDE studies that had robust comparisons to traditional anterior cervical fusion, but there is some data suggesting that this option is durable and at least no worse than anterior fusion at these longer intervals. Rates of reoperation for adjacent segment degeneration remain lower than for fusion, although the differences not reach statistical significant (Ghobrial et al. 2018). Sasso and Dejaegher have shown durable outcomes

at 10 years, with favorable results and reoperation profiles compared to anterior cervical fusion. Likewise, Pointillart recently reported excellent outcomes in 80% of their patients 15 years out from cervical disc arthroplasty (Sasso et al. 2017; Dejaegher et al. 2017; Pointillart et al. 2018).

Surgical Techniques: Lumbar Disc Arthroplasty

Indications

- Degenerative disc disease
  - Most often single level, although multilevel use has been reported.
  - Demonstrated on MRI, CT, and/or plain radiographs.
  - Utilization of discography for confirmation of degenerative disc disease being causative for low back pain is suggested in some prior studies and technique guides as some have found it helpful for predicting improved outcome after surgery; however subsequent studies have shown increased rates of degenerative disc disease progression with the use of discography (Colhoun et al. 1988; Carragee et al. 2009). At this time, use of discography remains controversial, although anecdotally seems to have largely fallen out of favor.
- L3-S1 levels
- Failure of conservative measures for at least 6 months

Contraindications

- Instability
  - Spondylolisthesis
  - Spondylolysis
- Deformity
- Severe facet degeneration
  - With or without hypertrophy resulting in lateral recess stenosis
- Herniated nucleus pulposus resulting in radiculopathy
- Osteoporosis or osteopenia (T-score less than −1.5)
  - Metabolic disease resulting in compromised integrity of a bone architecture and/or remodeling
- Infection
- Pregnancy
- Prior trauma or fracture at affected level
  - Large Schmorl's nodes involving endplate at the affected levels
- Vascular calcification
- Metal or materials allergy

Relevant Anatomy

For the lumbar total disc replacements discussed in this section, an anterior approach to the spine is utilized. This can be trans- or retroperitoneal, depending on surgeon preference. Some spine surgeons may utilize an access surgeon to perform the approach.

Vessels

- **Aorta** is the largest artery in the body and courses anterior to the spine, left of and ventral to the inferior vena cava. The bifurcation into the common iliac arteries often occurs near the L5 vertebral body. While injury to the aorta itself is rare, if the great vessels need to be mobilized proximal to the bifurcation, segmental lumbar arteries that come directly off the aorta must be identified, isolated, and ligated to prevent significant blood loss, which can be more difficult to control if the vessels retract when avulsed.
- **Inferior vena cava** (IVC) is rarely encountered as it is predominantly a right-sided structure, and most approaches are left sided to (1) avoid injury to the IVC and (2) because there often is a more favorable plane on the left compared to the right of the great vessels leading to the anterior spine. If the IVC or a direct branch going to it is injured, hemorrhage can be massive and swift.

- **Iliac arteries and veins** – Injury to the left common iliac vein is one of the most commonly reported vascular injuries sustained during this approach and can result in massive hemorrhage in a relatively short amount of time. Often, the vessel can be repaired and the remainder of the procedure completed. Anterior lumbar procedures targeted at the L5-S1 level are typically performed caudal to the bifurcation of the aorta and vena cava and between the common iliac arteries and veins. At more proximal levels rostral to the bifurcations, these vessels need to be mobilized to allow adequate access to the targeted disc spaces.
- **Segmental vessels including the iliolumbar vein** can also cause significant bleeding which can be difficult to control unless these vessels are anticipated, identified, and ligated. Particularly the iliolumbar vein, which can be a large but very thin-walled structure traversing from the posterior aspect of the psoas muscle coursing to the left common iliac or IVC at the L4–5 level. This structure can often be identified on preoperative imaging to facilitate planning; however the surgeon must be aware of this vessel to control a prior to avulsion and retraction into the psoas, which can make it particularly difficult to control.

Ureter is a retroperitoneal structure which is identified by its peristalsis and mobilized medially along with the peritoneal contents during a retroperitoneal approach. One must avoid injuring it.

Sympathetic plexus is a latticework of nerve fibers, the superior hypogastric plexus, that runs anterior to the spine and the great vessels and medial to the iliac vessels. Injury to this structure can result in sexual dysfunction, specifically retrograde ejaculation. Patients must be counseled preoperatively on this potential risk, and younger patients may wish to consider further family planning options prior to undergoing an anterior lumbar procedure. A retroperitoneal approach carries a lower risk of injury to the structure compared to a transperitoneal approach. Additionally, blunt or bipolar dissection is recommended at the level and depth of the vessels to minimize risk of injury to these nerve fibers. Although rare, sympathetic dysfunction may occur resulting in ipsilateral lower extremity vasodilation which can mimic deep vein thrombosis. Subjectively the contralateral leg may feel cool relative to the warm ipsilateral lower extremity. This dysfunction typically resolves with observation.

Positioning and Approach

The patient is positioned supine on a radiolucent operating table with the arms out to the sides or crossed over a pillow on the chest. Some surgeons advocate for placement of a bump beneath the sacrum to bring the lumbar spine into a more accessible position. It should be noted, however, that the bump should not be placed beneath the lordotic portion of the lumbar spine so as not to exaggerated lumbar lordosis which may result in improper implant positioning. If possible, the patient position on the operating table should facilitate storage of the fluoroscopy machine when not in use.

There are several options to gain anterior exposure to the lumbar spine such as trans- or retroperitoneal, midline or paramedian, open, mini open, or laparoscopic assisted. For an open, retroperitoneal approach, the incision is localized over the target disc space using lateral fluoroscopy. Subcutaneous dissection is performed down to fascia, which is also incised. The rectus is mobilized either medially or laterally, depending on the approach and the necessary trajectory. The preperitoneal space is identified and entered, and the peritoneum and its contents are mobilized medially to allow access to the retroperitoneum. The ureter should be identified in this plane and mobilized with the peritoneum. The great vessels are identified and gently mobilized as needed for access to the desired disc space. At L4–5, the iliolumbar vein is identified, ligated, and divided to

avoid inadvertent avulsion and hemorrhage. At L5-S1, the middle sacral artery is isolated and ligated to allow unimpeded access to this disc space. At the level of the vessels and spine, blunt and bipolar dissection is used to minimize risk of injury to the sympathetic plexus. Fixed retractors can then be placed. The targeted disc is confirmed with lateral fluoroscopy, and the midline is marked using AP fluoroscopy. A standard annulotomy and diskectomy are performed, avoiding violation of the endplates.

Implant-Specific Instrumentation

ProDisc-L II (DePuy Synthes) (Prodisc-L 2017) (Fig. 8)

- *Device Type*
  - Metal on plastic (polyethylene)
  - Ball and socket
- *Procedure*

  After a standard discectomy has been performed, the intervertebral space is distracted with the spreader. A trial is placed to assess the implant height, size, and degree of lordosis. The keel tract is prepared with the chisel. During this step, position and trajectory of the keel must be confirmed as this will establish the implant position. The prosthesis is modular such that there are several options for lordosis of each endplate and insert heights to most accurately reconstruct the native disc space. The selected prosthetic endplates are inserted. Disc space is distracted, and the polyethylene inlay is inserted into the caudal endplate. Final position is confirmed using lateral and AP fluoroscopy.

Postoperative Protocol

Much of the postoperative protocol is at the discretion of the surgeon. In general, avoidance of aggressive bending, twisting, or lifting is recommended for 6 weeks followed by gradual return to full activity thereafter. Postoperative bracing is utilized based on surgeon preference, but not required.

Complications

As can be seen with anterior lumbar interbody fusion, approach-related complications do occur. These include injuries to adjacent vasculature, sympathetic plexus, ureter, and rarely lymphatic ducts. The rates of these complications are similar as to what is seen in anterior lumbar interbody fusion (Blumenthal et al. 2005). Heterotopic ossification has been reported in up to 50% of patients; however this often does not result

Fig. 8 Prodisc-L prosthesis. (Reprinted with permission from Atkins, et al. *Lumbar Disc Arthroplasty.* In: Essentials of Spinal Stabilization. Holly L., Anderson P. (eds). Springer, Cham. 2017)

in inferior clinical outcomes (Park et al. 2018). Jackson et al. did report a case in which heterotopic ossification along with implant malposition resulted in a new radiculopathy (Jackson et al. 2015). Symptoms resolved with revision for implant removal, anterior interbody fusion, posterior decompression, and pedicle screw fixation. Implant-related complications such as subsidence, dislocation, or luxation have been reported (Kurtz et al. 2007; Kostuik 2004). Additionally, bearing surfaces do raise the concern abnormal wear, particulate degeneration, and adjacent inflammatory changes. There are case reports and small series of the instances resulting in inflammation and osteolysis. Authors have postulated that suboptimal local biomechanics such as adjacent level fusion, incorrect implant sizes, and impingement may all be contributing factors. Study of removed implants has demonstrated both abrasive and adhesive wear of the polyethylene (Kurtz et al. 2007; van Ooij et al. 2007). Finally, persistent pain postoperatively has been reported. This is also likely multifactorial. It is well-known that there are multiple possible pain generators in the lumbar spine, and disc replacement does not address all of these. Facet degeneration pre- or postoperatively may be may be a major contributor to ongoing pain. Of 91 patients at a single IDE site, 50% of failures were secondary to facet pathology (Pettine et al. 2017).

Revision Options

As is the case with cervical disc arthroplasty revision, the lumbar revision procedure performed ultimately depends on the underlying pathology to be addressed at the time of surgery. Options include revision for replacement of an arthroplasty device, anterior revision for lumbar interbody fusion with or without posterior instrumentation, or posterior lateral instrumented fusion alone without anterior revision. Repeating an anterior exposure may be needed for situations such as arthroplasty device migration but should otherwise be considered with caution as adhesions can be problematic, and there is higher risk of vascular and visceral injury.

Outcomes

The SB Charité lumbar prosthetic was implanted for a period of nearly 20 years. Despite its eventual withdrawal from the market in 2013, this lumbar device has the longest available follow-up data and permits inquiry into the longevity of lumbar total disc replacement systems. Lemaire and colleagues presented 10-year minimum follow-up results in their retrospective case series of 100 patients implanted with the SB Charité III between 1989 and 1993 for the indication of intractable discogenic back pain. The authors used a modified Stauffer-Coventry scoring system which expresses results as relative gain. A relative gain of $\geq$70% indicates an excellent outcome and is defined as no pain, no medication use, and resumption of activity in the same job after 3 months. Ninety percent of patients in their series had an excellent or good outcome at 10 years, and 92% of eligible patients returned to the work force in some capacity. Radiographic analysis at 10 years showed that the Charité maintained normal range of motion in 95% of patients with a mean flexion/extension arc of 10.3°. Five patients underwent secondary arthrodesis at the index level for poor outcomes and the symptomatic adjacent level disease reoperation rate was 2% (Lemaire et al. 2005). David et al. found very similar positive results (82% with excellent or good outcomes) in their 10-year minimum retrospective case series of 106 patients. These authors reported a 10% index level and a 3% adjacent level reoperation rate (David 2007). The longest prospective data reported is the 5-year results from the US FDA IDE randomized controlled trial comparing the Charité to lumbar fusion. Ninety patients randomized to the Charité group between 2000 and 2002 were available for follow-up 5 years later. Guyer et al. found that Oswestry Disability Index (ODI), SF-36, and Visual Analog Scale (VAS) scores maintained clinically significant improvements over baseline. Overall clinical success, defined by the FDA, was achieved in 58% of the Charité patients and 51% of the arthrodesis patients still after 5 years. Seven of 90 cases were reported as "failures" necessitating index level reoperation, and adjacent level disease

Fig. 9 ActivL prosthesis. (Reprinted with permission from Atkins, et al. *Lumbar Disc Arthroplasty.* In: Essentials of Spinal Stabilization. Holly L., Anderson P. (eds). Springer, Cham. 2017)

reoperation rates were 1.1% and 4.7% for the Charité and arthrodesis, respectively (Guyer et al. 2009).

Outcomes of the ProDisc-L (DePuy Synthes) lumbar artificial disc are perhaps the most relevant at this juncture given that it remains commercially available and has the longest track record. Park et al. followed 35 patients for a mean of 6 years. Subjective outcome surveys were quite encouraging as 31 of 35 patients reported being completely or somewhat satisfied with their results. Similarly, 21 of 35 reported that they would definitely or probably undergo lumbar total disc replacement again if represented the option (Park, Spine 2012). Per the FDA-defined clinical success criteria, 71% of the cases qualified (Park, Spine 2012) (Park et al. 2012). In another retrospective case series of 55 patients with an average follow-up of 8.7 years, 75% had excellent or good results (Tropiano et al. 2005). Prospective data also supports lumbar arthroplasty as a reliable alternative to arthrodesis. Siepe and colleagues prospectively reviewed 181 patients after a mean of 7.4 years and found that both VAS and ODI scores were improved with statistical significance compared to baseline preoperative values (Siepe et al. 2014). Eighty-six percent of their patients were highly satisfied or satisfied. They also reported a low adjacent level disease reoperation rate of 2.2% which was comparable to that of the Charité. The most influential data comes from this device's US FDA IDE randomized controlled trial which showed very comparable results at 5 years between the ProDisc-L and circumferential lumbar arthrodesis. FDA-defined clinical success was met by 54% of the lumbar arthroplasty cases and 50% of the fusion cases. Both groups maintained significant improvements in ODI and SF-36 scores compared with baseline values. Restoration of normal lumbar motion, dictated by level, was achieved in 92% of the ProDisc-L cases with a mean flexion-extension arc of 7.2°. The index level reoperation rate was lower in the arthroplasty group (8%) compared to arthrodesis (12%) (Zigler and Delamarter 2012).

There is no long-term follow-up data for the second FDA-approved lumbar total disc replacement system, the ActivL (Aesculap Implant Systems, Fig. 9). It has only been commercially available since 2015. Nonetheless, its 2-year follow-up data appears to show statistically superiority to its predecessors (Garcia et al. 2015).

Conclusion

The theoretical advantage of motion sparing technology for degenerative spinal pathology is appealing. There has been much research and progress on this topic of intervertebral disc replacement over the last several decades, and the future is promising. Despite the advances, an understanding of the failures remains necessary so as not to repeat them. Currently, cervical disc arthroplasty has outpaced lumbar disc arthroplasty. There are more FDA-approved cervical devices than there are lumbar devices, and anecdotally, cervical disc replacement is more

widely favored than lumbar. The greater success of cervical disc replacement may stem from the underlying indications when compared to that of lumbar disc replacement; cervical procedures are indicated for degenerative disc disease resulting in radiculopathy or myelopathy, which are more predictably treatable entities, whereas lumbar disc procedures are often contraindicated in the setting of radiculopathy and predominantly indicated in degenerative disc disease only with axial pain, which is a notoriously difficult entity and patient population to treat successfully and predictably. For both cervical and lumbar disc replacement, early and midrange follow-up are now becoming available up and seemingly favorable, but we will need to continue to follow these technologies for long-term data to show whether it is more definitively a durable alternative to arthrodesis.

Cross-References

- ▶ Adjacent-Level Disease: Fact and Fiction
- ▶ Biological Treatment Approaches for Degenerative Disc Disease: Injectable Biomaterials and Bioartificial Disc Replacement
- ▶ Cervical Arthroplasty: Long-Term Outcomes
- ▶ Cervical Spine Anatomy
- ▶ Cervical Total Disc Replacement: Biomechanics
- ▶ Cervical Total Disc Replacement: Evidence Basis
- ▶ Cervical Total Disc Replacement: Expanded Indications
- ▶ Cervical Total Disc Replacement: FDA-Approved Devices
- ▶ Cervical Total Disc Replacement: Heterotopic Ossification and Complications
- ▶ Cervical Total Disc Replacement: Next-Generation Devices
- ▶ Cervical Total Disc Replacement: Technique – Pitfalls and Pearls
- ▶ Lumbar TDR Revision Strategies
- ▶ Posterior Lumbar Facet Replacement and Interspinous Spacers
- ▶ Thoracic and Lumbar Spinal Anatomy

References

Baaj AA, Uribe JS, Vale FL, Preul MC, Crawford NR (2009) History of cervical disc arthroplasty. Neurosurg Focus 27(3):E10. https://doi.org/10.3171/2009.6.FOCUS09128

Basho R, Hood KA (2012) Cervical total disc arthroplasty. Glob Spine J 2(2):105–108. https://doi.org/10.1055/s-0032-1315453

Blumenthal S, McAfee PC, Guyer RD et al (2005) A prospective, randomized, multicenter Food and Drug Administration investigational device exemptions study of lumbar total disc replacement with the CHARITÉ artificial disc versus lumbar fusion: part I: evaluation of clinical outcomes. Spine 30(14): 1565–1575; discussion E387–E391

Bono CM, Garfin SR (2004) History and evolution of disc replacement. Spine J 4(6):S145–S150. https://doi.org/10.1016/j.spinee.2004.07.005

Bryan cervical disc surgical technique. January 2005:1–26

Buckwalter JA (1995) Aging and degeneration of the human intervertebral disc. Spine 20(11):1307–1314

Burkus JK, Traynelis VC, Haid RW, Mummaneni PV (2014) Clinical and radiographic analysis of an artificial cervical disc: 7-year follow-up from the Prestige prospective randomized controlled clinical trial: clinical article. J Neurosurg Spine 21(4):516–528. https://doi.org/10.3171/2014.6.SPINE13996

Büttner-Janz K, Schellnack K, Zippel H (1989) Biomechanics of the SB Charité lumbar intervertebral disc endoprosthesis. Int Orthop 13(3):173–176

Carragee EJ, Don AS, Hurwitz EL et al (2009) 2009 ISSLS Prize Winner: does discography cause accelerated progression of degeneration changes in the lumbar disc: a ten-year matched cohort study. Spine 34(21): 2338–2345. https://doi.org/10.1097/BRS.0b013e3181ab5432

Cavanaugh DA, Nunley PD, Kerr EJ, Werner DJ, Jawahar A (2009) Delayed hyper-reactivity to metal ions after cervical disc arthroplasty: a case report and literature review. Spine 34(7):E262–E265. https://doi.org/10.1097/BRS.0b013e318195dd60

Chang U-K, Kim DH, Lee MC, Willenberg R, Kim S-H, Lim J (2007) Changes in adjacent-level disc pressure and facet joint force after cervical arthroplasty compared with cervical discectomy and fusion. J Neurosurg Spine 7(1):33–39. https://doi.org/10.3171/SPI-07/07/033

Chen J, Wang X, Bai W, Shen X, Yuan W (2011) Prevalence of heterotopic ossification after cervical total disc arthroplasty: a meta-analysis. Eur Spine J 21(4):674–680. https://doi.org/10.1007/s00586-011-2094-x

Colhoun E, McCall IW, Williams L, Cassar Pullicino VN (1988) Provocation discography as a guide to planning operations on the spine. J Bone Joint Surg Br 70(2): 267–271. https://doi.org/10.1302/0301-620X.70B2.2964449

Cummins BH, Robertson JT, Gill SS (1998) Surgical experience with an implanted artificial cervical joint. J Neurosurg 88(6):943–948. https://doi.org/10.3171/jns.1998.88.6.0943

Cunningham BW, Kotani Y, McNulty PS, Cappuccino A, McAfee PC (1997) The effect of spinal destabilization and instrumentation on lumbar intradiscal pressure: an in vitro biomechanical analysis. Spine 22(22): 2655–2663

Datta JC, Janssen ME, Beckham R, Ponce C (2007) Sagittal split fractures in multilevel cervical arthroplasty using a keeled prosthesis. J Spinal Disord Tech 20(1):89–92. https://doi.org/10.1097/01.bsd.0000211258.90378.10

David T (2007) Long-term results of one-level lumbar arthroplasty: minimum 10-year follow-up of the CHARITÉ artificial disc in 106 patients. Spine 32(6): 661–666. https://doi.org/10.1097/01.brs.0000257554.67505.45

Dejaegher J, Walraevens J, van Loon J, Van Calenbergh F, Demaerel P, Goffin J (2017) 10-year follow-up after implantation of the Bryan cervical disc prosthesis. Eur Spine J 26(4):1191–1198. https://doi.org/10.1007/s00586-016-4897-2

Eck JC, Humphreys SC, Lim T-H et al (2002) Biomechanical study on the effect of cervical spine fusion on adjacent-level intradiscal pressure and segmental motion. Spine 27(22):2431–2434. https://doi.org/10.1097/01.BRS.0000031261.66972.B1

Garcia R Jr, Yue JJ, Blumenthal S et al (2015) Lumbar total disc replacement for discogenic low back pain. Spine 40(24):1873–1881. https://doi.org/10.1097/BRS.0000000000001245

Ghiselli G, Wang JC, Bhatia NN, Hsu WK, Dawson EG (2004) Adjacent segment degeneration in the lumbar spine. J Bone Joint Surg Am 86-A (7):1497–1503

Ghobrial GM, Lavelle WF, Florman JE, Riew KD, Levi AD (2018) Symptomatic adjacent level disease requiring surgery: analysis of 10-year results from a prospective, randomized, clinical trial comparing cervical disc arthroplasty to anterior cervical fusion. Neurosurgery 21(1):34. https://doi.org/10.1093/neuros/nyy118

Goffin J, Casey A, Kehr P et al (2002) Preliminary clinical experience with the Bryan cervical disc prosthesis. Neurosurgery 51(3):840–845; discussion 845–847. https://doi.org/10.1227/01.NEU.0000026100.14273.B3

Goffin J, Geusens E, Vantomme N et al (2004) Long-term follow-up after interbody fusion of the cervical spine. J Spinal Disord Tech 17(2):79–85

Gore DR, Sepic SB (1998) Anterior discectomy and fusion for painful cervical disc disease. A report of 50 patients with an average follow-up of 21 years. Spine 23(19): 2047–2051

Guyer RD, McAfee PC, Banco RJ et al (2009) Prospective, randomized, multicenter Food and Drug Administration investigational device exemption study of lumbar total disc replacement with the CHARITÉ artificial disc versus lumbar fusion: five-year follow-up. Spine J 9(5):374–386. https://doi.org/10.1016/j.spinee.2008.08.007

Hacker FM, Babcock RM, Hacker RJ (2013) Very late complications of cervical arthroplasty. Spine 38(26): 2223–2226. https://doi.org/10.1097/BRS.0000000000000060

Hallab NJ (2009) A review of the biologic effects of spine implant debris: fact from fiction. Int J Spine Surg 3(4):143–160. https://doi.org/10.1016/j.esas.2009.11.005

Heller JG, Sasso RC, Papadopoulos SM et al (2009) Comparison of BRYAN cervical disc arthroplasty with anterior cervical decompression and fusion: clinical and radiographic results of a randomized, controlled, clinical trial. Spine 34(2):101–107. https://doi.org/10.1097/BRS.0b013e31818ee263

Hilibrand AS, Carlson GD, Palumbo MA, Jones PK, Bohlman HH (1999) Radiculopathy and myelopathy at segments adjacent to the site of a previous anterior cervical arthrodesis. J Bone Joint Surg Am 81(4): 519–528

Hisey M, Zigler J, Jackson R et al (2016) Prospective, randomized comparison of one-level Mobi-C cervical total disc replacement vs. anterior cervical discectomy and fusion: results at 5-year follow-up. Int J Spine Surg 10:1–10. https://doi.org/10.14444/3010

Hutton WC, Toribatake Y, Elmer WA, Ganey TM, Tomita K, Whitesides TE (1998) The effect of compressive force applied to the intervertebral disc in vivo. A study of proteoglycans and collagen. Spine 23(23): 2524–2537

Jackson KL, Hire JM, Jacobs JM, Key CC, DeVine JG (2015) Heterotopic ossification causing radiculopathy after lumbar total disc arthroplasty. Asian Spine J 9(3):456–460. https://doi.org/10.4184/asj.2015.9.3.456

Janssen ME, Zigler JE, Spivak JM, Delamarter RB, Darden BV II, Kopjar B (2015) ProDisc-C total disc replacement versus anterior cervical discectomy and fusion for single-level symptomatic cervical disc disease. J Bone Joint Surg Am 97(21):1738–1747. https://doi.org/10.2106/JBJS.N.01186

Kostuik JP (2004) Complications and surgical revision for failed disc arthroplasty. Spine J 4(6):S289–S291. https://doi.org/10.1016/j.spinee.2004.07.021

Kurtz SM, van Ooij A, Ross R et al (2007) Polyethylene wear and rim fracture in total disc arthroplasty. Spine J 7(1):12–21. https://doi.org/10.1016/j.spinee.2006.05.012

Le H, Thongtrangan I, Kim DH (2004) Historical review of cervical arthroplasty. Neurosurg Focus 17(3):E1–E9. https://doi.org/10.3171/foc.2004.17.3.1

Lee CK, Langrana NA (1984) Lumbosacral spinal fusion. A biomechanical study. Spine 9(6):574–581

Lee J-H, Jung T-G, Kim H-S, Jang J-S, Lee S-H (2010) Analysis of the incidence and clinical effect of the heterotopic ossification in a single-level cervical

artificial disc replacement. Spine J 10(8):676–682. https://doi.org/10.1016/j.spinee.2010.04.017

Lemaire J-P, Carrier H, Sariali E-H, Sari Ali E-H, Skalli W, Lavaste F (2005) Clinical and radiological outcomes with the Charité artificial disc: a 10-year minimum follow-up. J Spinal Disord Tech 18(4):353–359

Leung C, Casey AT, Goffin J et al (2005) Clinical significance of heterotopic ossification in cervical disc replacement: a prospective multicenter clinical trial. Neurosurgery 57(4):759–763; discussion 759–763

Link HD (2002) History, design and biomechanics of the LINK SB Charité artificial disc. Eur Spine J 11(Suppl 2):S98–S105. https://doi.org/10.1007/s00586-002-0475-x

Martin BI, Mirza SK, Comstock BA, Gray DT, Kreuter W, Deyo RA (2007) Reoperation rates following lumbar spine surgery and the influence of spinal fusion procedures. Spine 32(3):382–387. https://doi.org/10.1097/01.brs.0000254104.55716.46

Matsumoto M, Okada E, Ichihara D et al (2010) Anterior cervical decompression and fusion accelerates adjacent segment degeneration: comparison with asymptomatic volunteers in a ten-year magnetic resonance imaging follow-up study. Spine 35(1):36–43. https://doi.org/10.1097/BRS.0b013e3181b8a80d

Mehren C, Heider F, Siepe CJ et al (2018) Clinical and radiological outcome at 10 years of follow-up after total cervical disc replacement. Eur Spine J 26(9):2441–2449. https://doi.org/10.1007/s00586-017-5204-6

Mobi-C cervical disc surgical technique guide. January 2016:1–32

Mummaneni PV, Burkus JK, Haid RW, Traynelis VC, Zdeblick TA (2007) Clinical and radiographic analysis of cervical disc arthroplasty compared with allograft fusion: a randomized controlled clinical trial. J Neurosurg Spine 6(3):198–209. https://doi.org/10.3171/spi.2007.6.3.198

Murrey D, Janssen M, Delamarter R et al (2009) Results of the prospective, randomized, controlled multicenter Food and Drug Administration investigational device exemption study of the ProDisc-C total disc replacement versus anterior discectomy and fusion for the treatment of 1-level symptomatic cervical disc disease. Spine J 9(4):275–286. https://doi.org/10.1016/j.spinee.2008.05.006

Park P, Garton HJ, Gala VC, Hoff JT, McGillicuddy JE (2004) Adjacent segment disease after lumbar or lumbosacral fusion: review of the literature. Spine 29(17):1938–1944

Park C-K, Ryu K-S, Lee K-Y, Lee H-J (2012) Clinical outcome of lumbar total disc replacement using ProDisc-L in degenerative disc disease: minimum 5-year follow-up results at a single institute. Spine 37(8):672–677. https://doi.org/10.1097/BRS.0b013e31822ecd85

Park H-J, Lee C-S, Chung S-S et al (2018) Radiological and clinical long-term results of heterotopic ossification following lumbar total disc replacement. Spine J 1–7. https://doi.org/10.1016/j.spinee.2017.09.003

Pettine K, Ryu R, Techy F (2017) Why lumbar artificial disk replacements (LADRs) fail. Clin Spine Surg 30(6):E743–E747. https://doi.org/10.1097/BSD.0000000000000310

Phillips FM, Geisler FH, Gilder KM, Reah C, Howell KM, McAfee PC (2015) Long-term outcomes of the US FDA IDE prospective, randomized controlled clinical trial comparing PCM cervical disc arthroplasty with anterior cervical discectomy and fusion. Spine 40(10):674–683. https://doi.org/10.1097/BRS.0000000000000869

Pickett GE, Mitsis DK, Sekhon LH, Sears WR, Duggal N (2004) Effects of a cervical disc prosthesis on segmental and cervical spine alignment. Neurosurg Focus 17(3):E5

Pointillart V (2001) Cervical disc prosthesis in humans: first failure. Spine 26(5):E90–E92

Pointillart V, Castelain J-E, Coudert P, Cawley DT, Gille O, Vital J-M (2018) Outcomes of the Bryan cervical disc replacement: fifteen year follow-up. Int Orthop 42:1–7. https://doi.org/10.1007/s00264-017-3745-2

Prestige LP cervical disc system surgical technique. January 2009:1–24

Prodisc-L surgical technique. January 2017:1–40

Punt IM, Visser VM, van Rhijn LW et al (2007) Complications and reoperations of the SB Charité lumbar disc prosthesis: experience in 75 patients. Eur Spine J 17(1):36–43. https://doi.org/10.1007/s00586-007-0506-8

Radcliff K, Davis R, Hisey M et al (2017) Long-term evaluation of cervical disc arthroplasty with the Mobi-C© cervical disc: a randomized, prospective, multicenter clinical trial with seven-year follow-up. Int J Spine Surg 11(5):244–262. https://doi.org/10.14444/4031

Reitz H, Joubert MJ (1964) Intractable headache and cervico-brachialgia treated by complete replacement of cervical intervertebral discs with a metal prosthesis. S Afr Med J 38:881–884

Sasso RC, Anderson PA, Riew KD, Heller JG (2011) Results of cervical arthroplasty compared with anterior discectomy and fusion: four-year clinical outcomes in a prospective, randomized controlled trial. J Bone Joint Surg Am 93(18):1684–1692. https://doi.org/10.2106/JBJS.J.00476

Sasso WR, Smucker JD, Sasso MP, Sasso RC (2017) Long-term clinical outcomes of cervical disc arthroplasty. Spine 42(4):209–216. https://doi.org/10.1097/BRS.0000000000001746

Sears WR, Duggal N, Sekhon LH, Williamson OD (2007) Segmental malalignment with the Bryan cervical disc prosthesis – contributing factors. J Spinal Disord Tech 20(2):111–117. https://doi.org/10.1097/01.bsd.0000211264.20873.78

Shim CS, Shin H-D, Lee S-H (2007) Posterior avulsion fracture at adjacent vertebral body during cervical disc replacement with ProDisc-C: a case report. J Spinal Disord Tech 20(6):468–472

Shriver MF, Lewis DJ, Kshettry VR, Rosenbaum BP, Benzel EC, Mroz TE (2015) Pseudoarthrosis rates in anterior cervical discectomy and fusion: a meta-analysis. Spine J 15(9):2016–2027. https://doi.org/10.1016/j.spinee.2015.05.010

Siepe CJ, Heider F, Wiechert K, Hitzl W, Ishak B, Mayer MH (2014) Mid- to long-term results of total lumbar disc replacement: a prospective analysis with 5- to 10-year follow-up. Spine J 14(8):1417–1431. https://doi.org/10.1016/j.spinee.2013.08.028

Szpalski M, Gunzburg R, Mayer M (2002) Spine arthroplasty: a historical review. Eur Spine J 11(Suppl 2):S65–S84. https://doi.org/10.1007/s00586-002-0474-y

Tropiano P, Huang RC, Girardi FP, Cammisa FP, Marnay T (2005) Lumbar total disc replacement. Seven to eleven-year follow-up. J Bone Joint Surg Am 87(3):490–496. https://doi.org/10.2106/JBJS.C.01345

Tu T-H, Wu J-C, Huang W-C et al (2011) Heterotopic ossification after cervical total disc replacement: determination by CT and effects on clinical outcomes. J Neurosurg Spine 14(4):457–465. https://doi.org/10.3171/2010.11.SPINE10444

Turner JA, Ersek M, Herron L et al (1992) Patient outcomes after lumbar spinal fusions. JAMA 268(7):907–911

Vaccaro A, Beutler W, Peppelman W et al (2013) Clinical outcomes with selectively constrained SECURE-C cervical disc arthroplasty. Spine 38(26):2227–2239. https://doi.org/10.1097/BRS.0000000000000031

van Ooij A, Oner FC, Verbout AJ (2003) Complications of artificial disc replacement: a report of 27 patients with the SB Charité disc. J Spinal Disord Tech 16(4):369–383

van Ooij A, Kurtz SM, Stessels F, Noten H, van Rhijn L (2007) Polyethylene wear debris and long-term clinical failure of the Charité disc prosthesis: a study of 4 patients. Spine 32(2):223–229. https://doi.org/10.1097/01.brs.0000251370.56327.c6

Wigfield CC, Gill SS, Nelson RJ, Metcalf NH, Robertson JT (2002) The new Frenchay artificial cervical joint: results from a two-year pilot study. Spine 27(22):2446–2452. https://doi.org/10.1097/01.BRS.0000032365.21711.5E

Zigler JE, Delamarter RB (2012) Five-year results of the prospective, randomized, multicenter, Food and Drug Administration investigational device exemption study of the ProDisc-L total disc replacement versus circumferential arthrodesis for the treatment of single-level degenerative disc disease. J Neurosurg Spine 17(6):493–501. https://doi.org/10.3171/2012.9.SPINE11498

Zou S, Gao J, Xu B, Lu X, Han Y, Meng H (2017) Anterior cervical discectomy and fusion (ACDF) versus cervical disc arthroplasty (CDA) for two contiguous levels cervical disc degenerative disease: a meta-analysis of randomized controlled trials. Eur Spine J 26(4):985–997. https://doi.org/10.1007/s00586-016-4655-5