



# Artificial disc replacement in spine surgery

Yahya A. Othman, Ravi Verma, Sheeraz A. Qureshi

Department of Orthopaedic Surgery, Hospital for Special Surgery, New York, NY, USA.

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*Correspondence to:* Sheeraz A. Qureshi. Department of Orthopaedic Surgery, Hospital for Special Surgery, New York, NY, USA. Email: sheerazqureshimd@gmail.com; QureshiS@hss.edu.

**Abstract:** Total disc replacement (TDR) is an innovative procedure that has gained traction in spine surgery. A large amount of data in the literature report on the short-term outcomes of TDR surgery favorably. However, surgeons remain reluctant to opt for TDR surgery due to uncertainty of long-term outcomes. Recently, long term data regarding TDR surgery has become available, with some studies showing superior outcomes to fusion surgery. The goal of this review is to synthesize and clinically contextualize the recent literature on TDR surgery. This article also provides brief discussion of the biggest challenges currently facing disc arthroplasties and the ways in which they are being tackled.

**Keywords:** Arthroplasty; cervical; lumbar; spine

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## Introduction

Degenerative disc disease (DDD) describes the gradual failure of the disc to perform its function resulting in worsened range of motion (ROM) and back pain (1,2). DDD can be attributed to aging, mechanical overloading, and certain genetic factors. The disc is an avascular structure, which makes it susceptible to damage and inability for reliable regeneration (3). This explains the wide prevalence of DDD (4).

Physiologically, the disc is responsible for acting as a shock absorber between the vertebrae (5). It also plays a role in maintaining spinal alignment and facilitating ROM. Degeneration and collapse of the intervertebral disc cause stress across the facet joint, impingement on neural structures, and strain on paraspinal muscles from loss of alignment (6). DDD can occur at any point across the spine, however it is most common in the cervical and lumbar regions causing neck and back pain, respectively. Although disabling, the majority of patients experience gradual resolution of symptoms without need for surgical intervention (7).

Conservative management for DDD fails in 20–30% of patients (8,9). Surgical options have traditionally involved discectomy and vertebral arthrodesis. Arthrodesis is effective at managing pain; however, it is associated with multiple complications that can negatively impact patient outcomes (10). Pseudarthrosis and instrumentation failure, are well known complications of arthrodesis surgery that have been well characterized (11,12). Furthermore, fusion of the vertebra reduces spinal ROM and also diverts spinal loads to the adjacent vertebrae (13). This unequal sharing of loads contributes to the development of adjacent segment disease (ASD) (14). Disc arthroplasty is a management option for DDD that aims to overcome the complications of fusion (15). It is a well-established surgical option that has been under investigation for more than 20 years. The principle behind disc arthroplasty is removing the pain-causing disc and restoring painless motion of the spine. Further, one of the goals of arthroplasty is to mimic the biomechanics of a healthy disc to allow for harmonic load sharing across the spine and avoid the development of ASD.

The literature on disc arthroplasty is expansive and can be challenging to interpret. There are many observational

studies, randomized controlled trials, and meta-analyses that seemingly report conflicting findings (13,16-33). Furthermore, arthroplasties are not a single entity. Lumbar and cervical artificial discs vary from each other, and implants within each category are different in their constructs and biomechanics. The aim of this paper is to present and contextualize the current available literature on disc arthroplasty, highlight recent advancement in the field, and report on significant basic science research to showcase the future direction of disc arthroplasty and how current challenges are tackled.

### **Artificial disc development: design, biomaterials, and tissue engineering**

Artificial discs have gone through a tremendous amount of transformation; there have been more than 30 designs before the first device was used clinically (34). Fernstrom was the first to describe a disc arthroplasty procedure in 1966. The device was a ball bearing implanted in the lumbar disc space. Initial outcomes of this arthroplasty showed promising results which encouraged development in the field.

The start of commercial-level arthroplasty occurred in the 1980s (15). The first lumbar implant used commercially was the Charite (DePuy, Raynham, MA, USA) which underwent 3 iterations, the last of which was introduced in 1987. The Charite III consisted of a pair of polymeric sliding cores affixed to 2 titanium coated metallic endplates. The Prodisc L (Synthes Spine, West Chester, PA, USA) was released soon after and also used a polymeric core and metallic endplates. The Maverick disc (Medtronic, Memphis, TN) was the first metal on metal articulating disc and was conceived in 2002. Since then, multiple artificial discs—lumbar as well as cervical—have been introduced, such as the active-L, Prestige, Mobi-C, O-Mav, Flexicore, Cadisc, and the M6s.

Although there is no equivalent to the implant endplate in the natural disc, they are a component in every disc implant and play a role in stabilization (35). Endplates can be made up of alloys from cobalt-chrome, stainless steel, titanium, or a metal and ceramic composite (36). The osteoconductive nature of titanium enhances the chance of solid adhesion with the adjacent vertebra. Furthermore, additional features of the endplate aid in stabilization and are in the form of spikes, keels, or screws. Although they support in fixation, these features do have a risk of impacting the vertebral endplate and can impose a challenge

for revision (37).

Artificial discs can be classified according to their structure as articulating or non-articulating (35). Articulating implants are composed of 2 or 3 solid discrete components that are combined in a ball-in-socket or ball-in-trough configuration. Ball-in-trough designs are more capable of allowing physiologic translational motion that ball-in-socket devices don't allow. However, articulating devices in general lack a compressible component that mimics the shock absorbance of the nucleus pulposus in the natural disc. This is unlike non-articulating devices, which are more complex in their structure and contain a soft core that both allows compression and a limited ROM (38).

Artificial discs aim to emulate the qualities of natural discs to allow them to perform the same function. The ProDisc, Charite, and Mobi-C implants all have a core made of ultra-high molecular weight polyethylene (UHMWPE). This material is inert, stiff, and resistant to delamination (39). This allows it to be used as a joint with low risk of free radical damage or sloughing due to constant abrasion. Furthermore, the smooth surface of UHMWPE is self-lubricating and is ideal for reducing friction forces in a joint surface (40).

However, the disc also plays a role in shock absorbance between the vertebra. The stiffness of UHMWPE does not allow any shock absorbance, and the compressive forces at stress points on the implant surface are implicated in the failure of these devices. Polycarbonate urethane (PCU) is a proposed polymer that allows a large degree of shock absorbance. PCU was first considered for use in hip and knee implants to allow for a longer life-time as it can function similar to cartilage (41). A new-generation, non-articulating disc implant, the M6 (Spinal Kinetics, Sunnyvale, CA), incorporates PCU in its core to add a shock absorbance capacity and a limited ROM. The M6 has only gained FDA approval for commercial use in 2019 (PMA Number P170036), and the success of PCU as well as the M6 implant in a large scale is yet to be seen.

Another approach to reproduce the function of the natural disc is to emulate its structure. The field of tissue engineering aims at creating scaffolds that, once impregnated with a cellular milieu, develop into a viable material that resembles the natural disc tissue at a structural level. There are increasing investigations using tissue engineering to recreate the annulus fibrosis (AF) as part of a whole disc arthroplasty. Structurally, the natural AF structure is made up of laminated layers with a high collagen content arranged at angles from each other (42).

Disc implants with the angle ply structure have already been created and investigated with animal models (43). Even though it is still in its early development stages, the field of tissue engineering is a promising solution for disc arthroplasty and currently under intensive investigation even in other areas of regenerative medicine.

Another classification for artificial implants is based on their ROM. The spectrum includes constrained, semi-constrained and unconstrained. This is defined in relation to physiologic ROM, being less than, equal to, or greater than physiologic ROM in constrained, semi-constrained, and unconstrained devices, respectively (44). The tradeoff for unconstrained devices is the excessive load placed on the facet joints which can lead to arthrosis. Additionally, constrained devices have a limited ROM, and their theoretical capacity to protect from adjacent segment disease is thus limited (45).

## **Lumbar TDR: surgical technique, indications, and outcomes**

### *Surgical technique*

After induction with general anesthesia, the patient is positioned supine on a radiolucent Jackson table with both the upper and lower limbs in abduction. AP and lateral images are captured to ensure visibility of the surgical level as well as neutral alignment of the lumbar spine.

The anterior approach is the most common access for insertion of the lumbar implant. A horizontal skin incision is placed over the center of the index level. The anterior aspect of the disc space is then exposed through retroperitoneal blunt dissection. The laterality of the approach depends on the level of the surgery and is mandated by the vasculature at that level. Above the aortic bifurcation for L4–L5 and higher, the vertebrae are accessed from the left. This is because the aorta lies to the left of the vena cava and is easier to identify and less likely to be damaged during retraction. At L5–S1, a left access places the inferior hypogastric plexus at risk of damage, and a right sided access is preferred.

Once the AF is exposed, the center of the vertebral disc space is identified through fluoroscopic imaging and marked on the cranial and caudal vertebrae. This facilitates accurate placement of the implant after preparation of the disc space. The AF is dissected anteriorly and a partial discectomy is performed, leaving the lateral and posterior aspects of the annulus intact. Special care is to be taken when dissecting

close to the osseous endplates, as preserving the integrity of the endplates is important for implant long term success. Implant trial, insertion and positioning vary depending on the implant used.

Once implantation is completed and satisfaction is verified fluoroscopically, the surgical site is irrigated and hemostasis is ensured via cautery or hemostatic agents. The rectus sheath and the linea alba are sutured and finally skin closure is performed.

### *Surgical considerations*

One of the goals of TDR surgery is to be able to restore the sagittal balance. Current literature suggests that increasing lordosis to reach physiologic sagittal alignment is correlated with improved clinical outcomes (46). While this is also true for TDR, there is evidence that reflects the importance of avoiding excessive lordosis in arthroplasty. Excessive lordosis may limit the ROM of the disc implant postoperatively as it causes the implant endplates to impinge on each other during extension. Furthermore, it can impose higher load on the implant causing wear that eventually results in implant failure (47).

It can be challenging to assess segmental lordosis intraoperatively, since the patient is in a supine position. Laouissat *et al.* propose a parameter that involves measuring the segmental angle intraoperatively while placing a spacer in the index disc space. This measurement was shown to reliably predict postoperative segmental lordosis in the standing position postoperatively (48).

Lateral, posterolateral, and transforaminal approaches have been described in the literature as alternatives to the anterior approach. Proponents of the lateral approach cite eliminating the need for an access surgeon as one of its main benefits. Furthermore, the lateral approach allows preservation of the anterior longitudinal ligament (ALL), which helps in maintaining sagittal balance and avoiding excessive ROM (37). The ALL plays a critical role in spinal stability. The importance of ALL for the success of TDR surgery is highlighted in a study that investigated the impact of reconstructing the ALL intraoperatively after an anterior approach. The results of that study showed that reconstructing the ALL improved sagittal alignment (49).

The outcomes of the lateral approach are comparable to TDRs performed with the anterior approach. Pokorny reported on the outcomes of 60 patients that underwent the lateral approach and reported clinical improvement comparable to that seen in an anterior approach.

Furthermore, this change was maintained at 92-month follow-up (17).

The transforaminal and posterolateral approach are less well investigated. The posterolateral approach has been studied on 6 cadaveric specimens showing relatively good outcomes. The transforaminal approach has only been investigated in biomechanical and finite element studies and was shown to be less successful. The biggest challenges facing transforaminal TDR are implant positioning and implant sizing which are restricted by the small surgical corridor.

Another novel surgical technique is the incorporation of facet replacement in addition to TDR. Facet arthrosis is correlated with disc degeneration and it is common for the two conditions to coexist. However, facet arthrosis is a contraindication for TDR. As a result, a large number of patients undergo fusion surgery as it is their only option. A biomechanical study was carried out by Nayak *et al.* to investigate lateral TDR with a unilateral facet joint replacement. The study showed no significant changes in spinal motion parameters when compared to an intact spine (50).

### Indications

Proper patient selection is imperative for success of TDR surgery. Lumbar TDR is preserved for patients with discogenic lumbar pain. This is because the procedure does not address posterior structures, and any pain originating posteriorly is unlikely to resolve after the surgery. Furthermore, since TDR preserves motion it is important that spinal stability is assessed. This is evaluated through the integrity of the facet joints as well as the global spine alignment. For instance, patients with Roussouly type 4 spinal alignment or with high pelvic incidence are less likely to achieve good outcomes from TDR surgery (51). In the same line of thought, patients with translational instability such as vertebral spondylolisthesis should not be opted for TDR surgery, as no added stability will be observed. Patients with poor bone quality are not good candidates for TDR as the implant is likely to not be stable. Patients with auto fusion such as those with ankylosing spondylitis are not fit for the surgery, as it is unlikely that the physiological ROM of the spinal segment will be restored (52).

### Outcomes

A large number of studies reporting on outcomes of

TDR are available. Gornet *et al.* conducted a study with a 5-year follow-up comparing single level TDR to fusion surgery (19). The investigators were able to demonstrate superiority of TDR at the 1 and 2-year follow-up according to patient reported outcomes, complications rate, and reoperation. They demonstrated noninferiority at the 5-year follow-up in the same measured outcomes. Furthermore, a prospective single arm trial for TDR showed that at 7–10 years follow-up, patients maintained sagittal balance and 55.6% of patients maintained a clinically significant improvement (27). A meta-analysis by Zigler *et al.* looking at outcomes 5 years post-operatively showed that TDR patients overall did better than their fusion counterparts (20). However a meta-analysis with a longer follow-up showed that the two cohorts are actually equivalent in terms of outcomes. (53).

TDR patients initially seem to fare better with regards to the development of ASD. Zigler *et al.* reported that TDR patients had a significantly lower incidence of symptomatic ASD compared to fusion patients at 5 years postoperatively (20). However, that difference was not significant in studies looking at 10-year follow-up, and reoperation at 10-year follow-up for TDR patients has been reported at 33% (54). In general, it seems that TDR patients achieve superior results to fusion in the early postoperative period, and equivalent results in late follow-up. It takes TDR patients longer to worsen compared to fusion patients (14). Studies have looked at multi-level lumbar TDR and reported good results. Rasouli *et al.* investigated 2-, 3-, and 4-level lumbar TDR surgery in a prospective cohort study of 159 patients (16). The results demonstrated preservation of preoperative ROM and sagittal alignment even at 72 months follow-up.

An alternative to multi-level TDR is hybrid surgery with 1 level TDR and 1 level fusion, commonly with an anterior lumbar interbody fusion (ALIF) procedure. Clinical data regarding patients undergoing hybrid surgery show that this technique is effective at controlling symptoms with patients that achieve clinically significant improvement according to multiple studies (26,55–57).

### Cervical TDR: surgical technique, indications, and outcomes

Cervical disc arthroplasty has been in practice in the US for more than 10 years. Non-inferiority as well as superiority have been well established in the literature, and more spine surgeons are confident to perform this surgery in place of fusion (58–60).



### *Surgical technique*

The patient is positioned supine on a radiolucent table with neutral alignment of the cervical spine. This alignment is accomplished by placing the patient's neck on a small roll and the head on a small cushion. Coronal spinal alignment is also necessary for the insertion of the disc, and is ensured by placing the patient's feet against a footboard. In addition, the shoulders are taped down to the footboard. Spinal cord monitoring leads are placed and monitored throughout the case. Visualization of the operative level using fluoroscopy is verified, and any necessary adjustments to positioning are performed. If proper visualization is not obtainable, it is advised not to go further with a cervical disc replacement and instead explore other options such as fusion.

A standard Smith-Robinson approach to anterior cervical spine is used, and fluoroscopy is used to confirm positioning. Once the position is confirmed, a self-retaining retractor is placed over the disc space and the operating microscope is brought to the surgical field. Discectomy and decompression are then performed at the operative level. The anterior annulus, nucleus pulposus, cartilaginous endplates, and the PLL are removed. Next, posterior osteophytes are removed using Kerrison rongeurs. Bilateral foraminotomies are then performed by resecting the uncovertebral joints which completely decompresses the spinal cord and nerve. Generous decompression and foraminotomies are warranted as, unlike in fusion, motion of compressed segments can exacerbate pain postoperatively.

Once decompression is complete, a lateral radiograph is taken to ensure endplates are parallel in the disc space before preparation is started. The implant is trialed under direct visualization and fluoroscopic confirmation to ensure fit.

Finally, the wound is irrigated and meticulous hemostasis is ensured using bipolar cautery. The wound is closed in a layered fashion and a drain is placed. Sterile dressings and a cervical collar are placed.

### *Surgical considerations*

Implant selection should be made to achieve a 5–7 mm postoperative disc height, as lower heights achieve a smaller sagittal ROM, and disc spaces more than 7 mm have a reduced capacity for lateral flexion (61,62).

Insertion and fixation vary depending on the device, however it is important that the device is inserted in parallel with the axis of the disc space to increase ROM of the spinal unit (63). For implants that are fixated on the anterior aspect

of the vertebra (Bryan, Medtronic), vertical alignment of the two vertebrae should be obtained before fixation. This can be achieved by shaving osteophytes anteriorly on the vertebra. For unconstrained and semi-constrained implants, position of the implant becomes critical. This is because the majority of the load is experienced at the implant-vertebra interface, and the risk of migration or failure is higher with incorrect positioning.

The decision to resect the posterior longitudinal ligament (PLL) depends on surgeon's preference and amount of decompression needed. Voronov *et al.* conducted a cadaveric study and noticed no difference in stability between resecting and keeping the PLL (64). They recommended that the type of implant, and more importantly the stiffness of the implant, should be considered when deciding whether to resect the PLL or preserve it.

Meticulous hemostasis and thorough irrigation should be performed throughout the procedure to avoid the risk of heterotrophic ossification (HO). The risk of HO varies among implants, as does the likelihood of posterior or anterior dislocation. Dislocation can most effectively be avoided through careful selection of implant size as well as preservation of the integrity of the endplate during preparation (65).

### *Indications*

Depending on patient characteristics, arthroplasty can carry a more or less favorable outcome compared to fusion. The ideal candidates for disc arthroplasty are patients with cervical radiculopathy or myelopathy due to discogenic degenerative disease that have failed conservative management (66). Furthermore, studies have shown that patients from all age groups equally benefit from undergoing cervical arthroplasty, with older patients maintaining cervical ROM at long term follow-up (67).

The index disc height should be 3 mm or more to ensure the insertion of the device does not result in a large distraction that imposes excessive stress on the posterior structures (68). Patients with major spondylosis or axial pain due to facet joint arthrosis are not ideal candidates, as it is unlikely that the surgery will address these symptoms (66).

Furthermore, preoperative instability due to previous surgery or degenerative disease, poor bone quality, and kyphotic deformity all contribute to failure of the device and therefore careful surgical planning is necessary when these pathologies are encountered (69).

### Outcomes

There is a large number of studies reporting on the outcomes of cervical TDR (58,61,70-77). According to a systematic review by Zou *et al.* which looked at studies comparing outcomes of 2 level arthroplasty to two level ACDF (78). Arthroplasty was associated with a significantly lower incidence of adjacent segment disease and lower rate of reoperation. However, this was concluded from studies with an average of about 2 years follow-up, and a large study with prolonged follow up is still needed. Furthermore, selection criteria is more restrictive for 2-level disc replacement surgery than for 2-level fusion surgery, and both levels must be meet the criteria for arthroplasty which can limit the number of appropriate candidates (79).

The impact of 2-level fusion on the cervical spine is two-fold compared to single level fusion. Two-level fusion surgery causes reduction in ROM that is more dramatic as well as a risk of adjacent segment disease that is higher (80). Furthermore, cervical disc arthroplasty for degenerative disease is more significantly superior for 2-levels compared to fusion (78). Finally, hybrid surgery for multi-level disease involving fusion of one level and disc replacement in the other has shown favorable outcomes compared to 2-level ACDF (81).

### The challenges facing TDR

Wear is the biggest challenge affecting implant success (40,82). Aseptic loosening propagated by implant wear is the most common cause for disc replacement failure. Implant wear causes deposition of debris in the area surrounding the prosthesis (83). This debris induces an inflammatory response which mimics a foreign body reaction with formation of granulomas and resorption of bone. Furthermore, the inflammatory milieu stimulates adjacent sensory fibers, potentiating the return of pain symptoms (83).

Many studies have investigated ways to reduce this immunologic reaction; immunomodulation is a possible therapeutic target for aseptic implant loosening. Several inflammatory markers have been identified in the pathway of inflammatory response leading to osteolysis (83). Etanercept—a TNF inhibitor—was hypothesized to be a viable therapy to limit osteolysis, however its efficacy is yet to be demonstrated clinically (36). More recent implants undergo an additional stage of gamma radiation that provides the implants with a higher degree of resistance to

oxidative damage. This will theoretically reduce the amount of wear debris (84).

Pain can also be propagated from the facet and sacroiliac joints (83). Patients with underlying low-grade facet arthrosis are likely to experience early return of pain post-operatively due to advancement in facet degeneration. In general, degeneration of the facet joint can be attributed to excessive loading on the facet due to loss of supportive ligaments. Interestingly, facet joint arthrosis was also found to occur more frequently in arthroplasty done in the l5-s1 level compared to other levels (15).

Surgical site infection is a rare but possible etiology of implant loosening (85). De la Garza-Ramos *et al.* conducted an analysis of the NESQIP database for all spinal procedures that included 36,440 patients (86). Arthroplasty had the lowest rate of infection (0.00%), while posterolateral fusion that had an infection rate of 1.04%.

HO is another possible complication after TDR surgery (29). HO can limit spinal motion and provoke ASD or can cause radiculopathy symptoms to develop (87). The incidence of HO after TDR ranges from 20% to 50% at 5 years, and can be as high as 71% at 10 years (29). Although HO significantly affects ROM, it has been shown in multiple studies that it does not produce worse patient outcomes (29,88).

### Conclusions

With the advent of new generation implants, TDR has reemerged in the field of spine surgery. A large amount of data is published in the literature showing favorable outcomes for TDR compared to fusion surgery. The general trend across studies reflects that TDR patients do experience a similar deterioration to fusion patients, however at a much later time. The biggest challenge for TDR surgery is optimization of the available implants to minimize wear and extend longevity.

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### Footnote

*Conflicts of Interest:* Dr. Sheeraz A. Qureshi: currently receiving Consulting Fees from Stryker K2M, Globus Medical, Inc., Paradigm Spine; Shareholder Interest in Avaz Surgical, Vital 5; and Royalties from RTI, Stryker

K2M; Medical/Scientific Advisory Board member at Spinal Simplicity, Lifelink.com; Board membership at Healthgrades, Minimally Invasive Spine Study Group. The other authors have no conflicts of interest to declare.

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