Cervical Total Disc Replacement: Next-Generation Devices

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Abstract

Cervical disc arthroplasty techniques were developed as an alternative to fusion in order to preserve natural motion and reduce the risk of adjacent segment degeneration in the appropriately selected patients with cervical myeloradiculopathy. These arthroplasty implants must provide stability, preserve physiologic motion, and replicate the kinematic signature of the natural disc. There are currently eight cervical arthroplasty implants approved by the Food and Drug Administration (FDA) for use in the United States. The majority of approved

implants follow a metal on polyethylene ball-in-socket or saddle-type design. Over the past decade, there has been an explosion of cervical arthroplasty implant designs each with their own advantages and disadvantages. The purpose of this chapter is to review the biomechanics and kinematics of the natural cervical disc. We will also review available in vivo and ex vivo literature on novel elastomeric compression, hydraulic, and next-generation ball-in-socket cervical arthroplasty designs.

Keywords

Cervical spondylosis · Arthroplasty · Radiculopathy · Myelopathy · Novel implants

Introduction

Motion-preserving cervical disc arthroplasty implants were developed as an alternative to fusion in order to preserve natural motion and cervical biomechanics and reduce the risk of adjacent segment disease for patients with cervical radiculopathy or myelopathy (Hilibrand et al. 1999). The goals of cervical disc arthroplasty are to restore disc and foraminal height, preserve physiologic motion, and provide long-term stability (Cepoiu-Martin et al. 2011; McAfee 2004; Mummaneni et al. 2007). There are currently eight cervical arthroplasty implants approved by the Food and Drug Administration (FDA) for clinical use. These include the Prestige ST and LP (Medtronic), Bryan (Medtronic), ProDisc-C (Centinel Spine), SECURE-C (Globus Medical), Porous Coated Motion (PCM) (NuVasive), Mobi-C (LDR), and the recently approved M6-C Artificial Cervical Disc (Orthofix). The majority of currently approved designs involve a bi-articulating ball-in-socket type design with a polyethylene core and metal (titanium or cobalt chrome) endplate. Most endplate designs include a keel for initial stability and textured surface to promote long-term bony ingrowth (Staudt et al. 2018).

Physiologic Kinematics

A healthy cervical intervertebral disc is viscoelastic and allows for three-dimensional motion in sagittal, coronal, and axial planes. Physiologic motion of a normal cervical segment allows for 15° of flexion-extension, 4° of lateral bending, and 5° of axial rotation in each direction (Holmes et al. 1994; Iai et al. 1994; Ishii et al. 2006). Additionally, there is a linear coupling of ipsilateral lateral bending and axial rotation resulting from facet and uncinate process orientation in each cervical segment (Bogduk and Mercer 2000; Patwardhan et al. 2012; Senouci et al. 2007). The physiologic sagittal center of rotation (COR) varies by cervical segment. The flexion-extension COR at the C5–C6 segment occurs at the midpoint of the superior endplate of the C6 vertebrae. The COR occurs at a point more caudad and dorsal in upper cervical segments and more cephalad in lower segments (Bogduk and Mercer 2000; Hwang et al. 2008; Patwardhan et al. 2012). An arthroplasty device should replicate both physiologic range of motion (ROM) and maintain a natural COR. An arthroplasty device that alters segments of physiologic COR may result in abnormal translations of the adjacent vertebrae during motion, unnatural forces across the segment including the facet joints and uncinate impingement. These abnormal forces may result in limited motion, pain, or ultimately facet joint or adjacent segment degeneration (Bogduk and Mercer 2000; Patwardhan et al. 2012; Pickett et al. 2006).

The viscoelastic cervical disc demonstrates nonlinear flexion-extension load-displacement curve. This characteristic allows for motion with minimal energy expenditure around the neutral zone, termed high flexibility zone. Increasing stiffness outside this high flexibility zone prevents damaging motion beyond the physiologic range. This graded resistance to angular motion also allows for energy dissipation, thereby reducing forces across index and adjacent segments under physiologic load (Panjabi 1992; Patwardhan et al. 2012). Additionally, the viscoelastic nature of the nucleus pulposus allows the disc to conform under compressive loads and act as a shock absorber, thereby reducing force across adjacent

segments and facets (Lazennec et al. 2016). The ideal cervical arthroplasty implant allows for compressibility and graded resistance to motion. Replicating this kinematic signature will reduce shear stresses across the facet joints and adjacent segments and improve implant longevity. First-generation ball-in-socket designs do not allow for compressibility or graded resistance to motion. Elastomeric cervical disc implants were developed as an alternative with these physiologic biomechanical characteristics in mind. Elastomeric compression devices are primarily designed with a polyurethane core that theoretically allows for motion under compression and graded resistance mimicking that of the native disc. To date, there are only a few cervical disc replacement designs that claim to fit this description. These include the M6-C Artificial Cervical Disc (Orthofix), Freedom Cervical Disc (FCD, AxioMed LLC), Cadisc-C (Rainier), and CP-ESP (FH Orthopedics) (Chin et al. 2017; Staudt et al. 2018).

Design Considerations

Multiple characteristics should be considered when designing and evaluating cervical arthroplasty devices. These include articulating surface design, mono or multipiece implant, constraint, materials, and fixation methods. The majority of cervical devices contain a mono or bi-articulating surface. First-generation implants use a ball-in-socket or saddle articulation design. Next-generation implants take advantage of these traditional designs but also include elastomeric and hydraulic-type designs. Implants may exist as a single monoblock or multipiece design. Experience with hip and knee arthroplasty would suggest that monoblock designs may predispose to increase stress across the implant/bone interface leading to early failure. Modular multipiece implants may reduce stress across adjacent interfaces and provide flexibility with sizing, though multipiece implants with more articulating surfaces inherently have more methods of failure. Certain first-generation ball-in-socket designs have highly congruent articulations with a resulting fixed COR. As a result, precise implant position is necessary for restoration of physiologic COR, which varies by cervical segment (Bogduk and Mercer 2000; Hwang et al. 2008; Patwardhan et al. 2012). Other designs that allow for some translation will have a mobile COR and theoretical flexibility in implant position and may accommodate segmental differences. Constraint is defined by the amount of motion in all directions allowed by the implant. Implants may be constrained, unconstrained, or semiconstrained. Constrained designs provide greater stability but may prevent physiologic motion thereby increasing stress on the implant/bone interface, adjacent segments, and facet joints. On the other hand, unconstrained designs may be unstable under physiologic loads. The majority of cervical arthroplasty designs are semiconstrained providing stability with physiologic motion.

Most currently approved cervical arthroplasty implants are made of a metal endplate (titanium, chrome/cobalt, stainless steel) with a polyethylene or polyurethane center. This basic design was born from hip and knee arthroplasty experience, providing a low-friction bearing surface with stable bone interface. Endplate metals offer different advantages and disadvantages based on modulus, stress shielding, biocompatibility, corrosion resistance, and advanced imaging metal artifact. Newer designs are taking advantage of polyetheretherketone (PEEK) and ceramic materials thereby improving MRI compatibility. Articulating surfaces, whether they are metal on metal, metal on polyethylene, or metal on polyurethane, have different wear debris profiles. Wear debris may result in osteolysis, bone loss, loosening, and ultimate implant failure as seen in hip and knee arthroplasty. Metal on metal articulations have been largely abandoned due to concerns for metal wear debris. Overall, the long-term wear profiles of polyethylene and polyurethane devices in the cervical spine are largely unknown. Finally, the majority of devices contain metal spikes or keels for initial fixation into the adjacent vertebral endplates. Long-term fixation is achieved by bony ingrowth into porous-coated (calcium phosphate, hydroxyapatite, and plasma-sprayed titanium) surfaces (Staudt et al. 2018).

Elastomeric Implants

M6-C Artificial Cervical Disc

The M6-C Artificial Cervical Disc Implant (Orthofix) is a next-generation non-constrained viscoelastic compression-type implant. The nucleus core is made of viscoelastic polyurethane surrounded by ultrahigh-molecular weight polyethylene fiber designed to mimic the nucleus and annulus, respectively, and mimic the physiologic properties of the natural disc (Fig. 1). This physiologic core is attached to two titanium endplates and surrounded by a sheath to prevent wear debris elution and tissue ingrowth. Both titanium endplates contain three fins for provisional fixation and titanium plasma spray coating to promote bony ingrowth. Biomechanical analysis of the M6-C design has demonstrated physiologic ROM, COR, and stability in cadaveric specimens. Patwardhan et al. evaluated the biomechanics of an implanted the M6-C artificial disc at the C5–C6 segment in 12 cadaveric specimens. ROM in flexion-extension, lateral bending, axial rotation, coupled motion, stiffness, and COR was evaluated using digital video fluoroscopic images under 1.5 Nm force moments and compared to control segments. They demonstrated implantation of the M6-C prosthesis within 1 mm of the disc-space midline closely replicated control segment COR and ROM in flexion-extension. Additionally, implantation in a more posterior position did not significantly affect ROM, coupling, or stiffness, suggesting an advantage to and flexibility of implant insertion associated with this novel elastomeric implant (Patwardhan et al. 2012). An initial multicenter FDA-regulated feasibility study evaluated 24-month clinical and radiographic outcomes of 30 patients undergoing one- or two-level M6-C prosthesis implantation with 24-month follow-up. They demonstrated improvement in Neck Disability Index (NDI) and Visual Analog Scale (VAS) neck and arm scores at all time points. No patients experienced surgical or neurologic complication. Radiographic disc height increased in all patients, while global and segment ROM in flexion-extension and lateral bending was maintained (Lauryssen et al. 2012). The results of the feasibility study suggested that the M6-C produces excellent results similar to current approved implants and suggested further prospective studies are necessary to determine the motion provided by the elastomeric compression design improves long-term clinical outcomes and reduces adjacent segment disease (Lauryssen et al. 2012). A recent retrospective study by Thomas et al. in Belgium evaluated clinical outcomes of 33 patients who underwent M6-C arthroplasty for spondylotic radiculopathy or myelopathy with mean 17.1-month follow-up. All patients demonstrated improvement in NDI, VAS arm and back, and

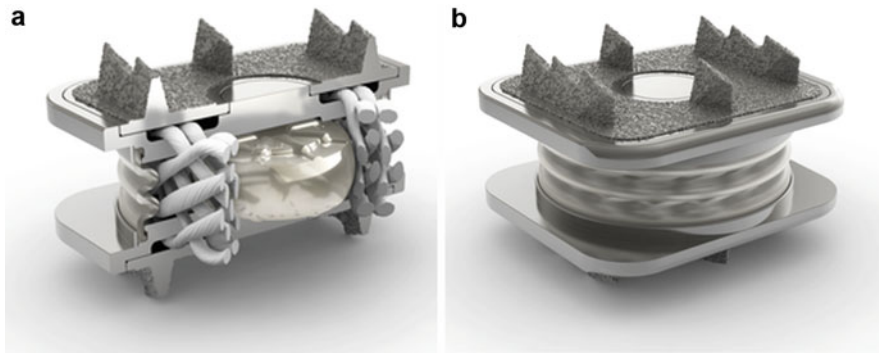

Fig. 1 (**a**) Cutaway schematic of the M6-C Artificial Cervical Disc Implant. It demonstrates viscoelastic polyurethane nucleus core surrounded by ultrahigh-molecular weight polyethylene fiber mimicking the nucleus and annulus of the natural disc. (**b**) Exterior schematic of M6-C Artificial Cervical Disc Implant demonstrating physiologic core attached to two titanium endplates. The core is surrounded by an external sheath to prevent tissue ingrowth and elution of wear debris. Each titanium endplate contains three fins for provisional fixation and titanium plasma spray coating to promote bony ingrowth

SF-36 scores. Four patients experienced device-related complications, two with endplate subsidence, one with implant loosening after motor vehicle collision, and one with immobility due to heterotopic ossification. All four of these patients had a history of previous cervical surgery. They concluded that the M6-C prosthesis is a good addition to the cervical arthroplasty options, though should be avoided in patients with history of previous cervical surgery (Thomas et al. 2016). Early reports on the FDA Investigational Device Exemption (IDE) outcomes data demonstrated favorable outcomes of 83 patients who underwent M6-C implantation at 12 (Phillips et al. 2017) and 24 months (Sasso et al. 2018) follow-up. There was significant improvement in the mean VAS neck and arm scores and index level lordosis. Mean index level ROM increased slightly from 7.8° preoperatively to 8.1 at 2 years. There was radiographic evidence of subsidence in three cases, no evidence of migration, and no revision procedures in the follow-up period (Phillips et al. 2017; Sasso et al. 2018). Further long-term studies with larger patient cohorts are needed to determine the effects on development of adjacent segment disease and long-term wear properties. The M6-C implant has recently received FDA approval for use.

Freedom Cervical Disc

The Freedom Cervical Disc (AxioMed) is a monoblock viscoelastic design consisting of an elastomeric core fixed to two titanium plates. The elastomeric polymer core consists of a silicone polycarbonate urethane copolymer. This polymer is molded and bonded to two titanium-retaining plates. Both titanium plates have a porous bead coating designed to engage and allow for bony ingrowth between the cephalad and caudad endplates. The Freedom Cervical disc is created with 8 degrees of lordosis and available in heights ranging from 5.7 to 6.9 mm. The prosthesis is designed to mimic a normal physiologic cervical disc by establishing appropriate alignment and lordosis, viscoelasticity to mimic load sharing, and stable range of motion in flexion, extension, lateral bending, and rotation. Surprisingly there are no biomechanical studies published to confirm the kinematic features claimed by the manufacturer. Specifically, there is no data regarding the stiffness of this monoblock polymer prosthesis and concerns for resultant high bone-implant forces.

The Freedom Cervical disc has undergone previous pilot studies outside the United States but is not currently approved for use within the United States (Chin et al. 2017; Staudt et al. 2018). One study by Chin et al. reported on the 2-year post market clinical outcomes of the Freedom Cervical Disc in Europe. A total of 39 patients with cervical radiculopathy at 5 institutions underwent one- or two-level cervical disc arthroplasty using the Freedom Cervical Disc. At 2 years clinical follow-up, all patients demonstrated improvement in NDI and VAS neck and arm pain scores. There were no new neurologic symptoms or device-related complications. ROM was surprisingly not evaluated in this study. They concluded that the Freedom Cervical Disc performed as expected in the appropriately selected patients with one- and two-level degenerative disc disease (Chin et al. 2017). This single study is limited by the number of patients and lack of long-term follow-up. Criticisms of this implant design include concerns regarding a single polymer of unknown compressibility matching physiologic properties of the native disc (Staudt et al. 2018).

CP-ESP Cervical Disc

A similar design, the CP-ESP cervical disc prosthesis (FH Orthopedics) is an evolution of the LP ESP lumbar prosthesis that has been implanted in Europe for over 10 years. The CP-ESP disc is a monoblock elastomeric implant with a central polycarbonate urethane (PCU) core fixed to two titanium endplates. Both endplates contain anchoring pegs, textured titanium, and hydroxyapatite layers to provide preliminary fixation and allow for bony ingrowth. The PCU core demonstrates resistance to oxidation both in vivo and ex vivo (Kurtz et al. 2007; Lazennec et al. 2016). The core is attached to the endplates via adhesion molding with peg and groove design without the

use of adhesives avoiding the risk of fluid infiltration and fatigue fractures. This design also allows the implant to replicate the anisotropy of a healthy disc, allowing for controlled compression while avoiding shear in flexion and extension. Mechanical analysis demonstrates a physiologic flexion/extension arc of 14°, lateral bending of 12°, and rotation of 8°. The CP-ESP implant is available in 5, 6, and 7 mm heights with various anterior-posterior and lateral dimensions.

A biomechanical assessment of wear debris and fatigue measured using a three-axis motion simulator over the course of ten million cycles demonstrated loss of height ranging from 0.02 to 0.12 mm and no detectable wear debris. Lazennec et al. prospectively evaluated 1- and 2-year clinical and radiographic outcomes of 62 patients who underwent one- or two-level cervical disc arthroplasty using the CP-ESP prosthesis. At both time points, all patients demonstrated improvement in NDI and VAS neck and arm scores. They also demonstrated improved radiographic range of motion at the index levels. No patients experienced implant-related complications or revision procedures during follow-up (Lazennec et al. 2016). Though this design is available for use in Europe, it is not currently under FDA review (Staudt et al. 2018).

Cadisc-C

The Cadisc-C (Ranier Technology) is an evolution of the Cadisc-L design for lumbar disc disease. This unique monoblock elastomeric design consists of polycarbonate-polyurethane nucleus with calcium phosphate coating without an associated metal endplate. The polycarbonate-polyurethane implant contains a lower modulus "nucleus" integrated into a surrounding higher modulus "annulus" allowing it to more accurately mimic the biomechanics of the natural intervertebral disc (McNally et al. 2012; Rieger 2014). The lack of metallic endplate and articulating surfaces is theorized to reduce potential for wear debris (McNally et al. 2012). Though, concern exists regarding the all polymer monoblock design lack of fixation and potential for migration. There is also no published data regarding wear debris profile of this design (Staudt et al. 2018). Currently, prospective trials are underway evaluating clinical outcomes of the Cadisc-C design in Germany (Rieger 2014).

Next-Generation Pivot/Ball Type Artificial Discs

Synergy Cervical Disc

The Synergy (Synergy Disc Replacement) Cervical Disc prosthesis is a next-generation ball-in-socket cervical disc comprised of bi-articulating titanium endplates with an ultrahigh-molecular weight polyethylene core. Bony fixation is augmented by six plasma-sprayed titanium "teels" (a combination of teeth and keels) on each articulating surface. Its three-piece design is MRI compatible and is available in 5 or 6 mm height options. The Synergy device also has a proprietary geometry which incorporates 0° or 6° of cervical lordosis (Staudt et al. 2018). Synergy was compared to two similar constrained ball and pivot arthroplasty designs (Bryan and ProDisc-C) in a retrospective study of 60 patients undergoing single-level cervical disc arthroplasty for cervical radiculopathy. Pre- and postoperative ROM along with dynamic lateral cervical spine imaging were assessed for each group. The Synergy cohort showed the least variability in change of sagittal alignment, achieving six degrees of lordosis on average with maintenance of cervical ROM achieved in all groups (Lazaro et al. 2010). A recent retrospective cohort study compared both the clinical outcomes and postoperative sagittal alignment of patients undergoing single-level surgery for cervical radiculopathy or myelopathy. Forty patients in the arthroplasty group were compared to 33 patients in the single-level fusion group with a minimum follow-up of 24 months. Both the arthroplasty and ACDF groups showed significant improvement in NDI and VAS neck and arm scores. The arthroplasty group maintained an average cervical lordosis of 6 +/− 2.7°, while the ACDF group demonstrated an

average of 4 +/− 2.4° of lordosis. The authors concluded that the Synergy system demonstrated comparable outcomes and improved sagittal alignment in comparison to cervical fusion (Yucesoy and Yuksel 2017). While it has undergone various stages of testing and pilot studies, the Synergy arthroplasty system lacks FDA approval and is not currently available in the US market.

Baguera C

The Baguera C (Spineart) is a novel ball-in-socket implant with a mobile core designed as a shock absorber. The mobile core is made of ultrahigh-molecular weight polyethylene (UHMWPE) nucleus that articulates with two titanium endplate components. The titanium endplates contain a bioceramic internal coating in contact with the UHMWPE nucleus and a porous titanium exterior intended for endplate ingrowth. Each endplate contains three fins intended to provide initial stability. The nucleus allows to 0.3 mm anterior to posterior translation, 2° rotation, and 0.15 mm elastic deformation mimicking that of the physiologic disc. One biomechanical analysis demonstrated reduced core contact pressures and liftoff throughout ROM compared to ProDisc-C (Centinel Spine) and Discocerv (Alphatec) using a cervical spine finite element model (Lee et al. 2016). Fransen et al. performed a retrospective registry analysis of 99 patients at 5 European investigational centers undergoing one- or two-level cervical arthroplasty for radiculopathy or myelopathy using the Baguera C implant. They demonstrated a decreased range of motion from 10.2° preoperatively to 8.7° for single-level procedures and from 9.8° to 9.1° for two levels at 2 years radiographic follow-up. They also demonstrated evidence of heterotopic ossification in 54% of patients. None demonstrated radiographic evidence of subsidence, kyphosis, or degeneration of the adjacent disc (Fransen 2016). While lack of radiographic evidence of adjacent segment disease is encouraging, larger long-term studies are needed to determine the efficacy of the implant. Additionally, the mobile nucleus design may theoretically predispose to long-term wear debris and potential for osteolysis as seen in hip and knee arthroplasty.

Simplify Cervical Disc

The Simplify disc has completed one- and two-level IDE study but is not yet received FDA approval. It is a semiconstrained design with titanium plasma-sprayed PEEK endplates with a retention ring housing a mobile ceramic core. Simplify is a modern generation disc with novel biomaterials (PEEK and ceramic) which provide for positive imaging characteristics.

Conclusions

The goal of motion-preserving cervical arthroplasty devices is to restore natural kinematics and motion under physiologic load and prevent degeneration of adjacent segments. Traditional, first-generation cervical arthroplasty devices contain ball-in-socket type designs and do not allow for physiologic coupled motion and compressible graded resistance. As a result, these designs may predispose to adjacent segment and facet stress predisposing to facet degeneration, pain, reduced motion, and degeneration. Early biomechanical evidence suggests that next-generation elastomeric compression devices may better replicate physiologic coupled motion and graded resistance. Further studies are necessary to determine the wear properties, durability, and long-term outcomes of these novel implants.

Cross-References

- ▶ Cervical Total Disc Replacement: Biomechanics
- ▶ Cervical Total Disc Replacement: Evidence Basis
- ▶ Cervical Total Disc Replacement: Expanded Indications
- ▶ Cervical Total Disc Replacement: Heterotopic Ossification and Complications

▶ Cervical Total Disc Replacement: Technique – Pitfalls and Pearls

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