Cervical Total Disc Replacement: FDA-Approved Devices

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Abstract

Cervical total disc replacement is a routinely used treatment for radiculopathy due to degenerative disease of the cervical spine. The procedure originated to avoid some of the complications seen with the traditional anterior cervical discectomy and fusion. Appropriate patient selection is paramount to obtain acceptable patient outcomes, with particular indications and contraindications for these procedures. As the procedure gained more acceptance, several cervical artificial discs have been developed and, subsequently, approved by the US Food and Drug Administration (FDA). Each of the eight FDA-approved devices is briefly reviewed in this chapter including outcomes from device-specific studies.

Keywords

Artificial disc · Cervical · Disc replacement · FDA-approved · Outcomes

Introduction

Anterior cervical decompression and fusion (ACDF) is one of the most common surgeries done worldwide to decompress the cervical canal, provide stabilization, and restore the normal lordosis of the cervical spine (Cloward 2007; Smith and Robinson 1958). It has been utilized in the treatment of degenerative disc disease, cervical radiculopathy, myelopathy, instability, and segmental deformity. Fusion rates for ACDFs are reported above 95%, and this fusion has been shown to cause a change in motion characteristics of the adjacent segments (DiAngelo et al. 2003; Eck et al. 2002). The change in the kinematics of adjacent levels may be responsible for increased risk of adjacent segment degeneration (Hilibrand et al. 1999; Dohler et al. 1985).

Cervical total disc replacement was developed to avoid some of these complications seen with ACDF. Preservation of the motion segments after total disc replacement surgery may reduce or delay the progression of adjacent segment disease by maintaining motion as well as normal segmental lordosis and anatomic disc space height (Fuller et al. 1998). Indications and contraindications are reviewed in this chapter as not all patients who are candidates for ACDF are candidates for total disc replacement.

Acceptance of this procedure has led to the development of numerous artificial disc designs. Eight devices have been approved by the US Food and Drug Administration (FDA) after thorough investigation through investigation device exemption (IDE) studies. Each of the eight FDA-approved devices (Prestige ST, Bryan, ProDisc-C, Secure-C, PCM, Mobi-C, Prestige LP, M6-C) and their outcomes are briefly discussed in this chapter. All eight artificial discs are FDA-approved for one-level use from C3-7. Only two artificial discs, Mobi-C and Prestige LP, are FDA-approved for two-level use. Most of the artificial disc designs have either uni- or biarticulating surfaces, although the newest FDA-approved device, M6-C, has a non-articulating, compressible core. Most of these discs are metal-on-polymer (M-o-P), although the Prestige ST and Prestige LP represent metal-on-metal (M-o-M) designs. Despite the controversy surrounding M-o-M total hip arthroplasty implants, there have been no widespread reports of M-o-M cervical artificial discs causing complications such as elevated serum metal ion levels, osteolysis or pseudotumor formation (Coric et al. 2011).

Rationale for Total Disc Replacement

As mentioned, despite long-term clinical success of ACDF, it has been associated with the development of adjacent segment degeneration. This

degeneration can be associated with symptoms such as radiculopathy, myelopathy, or neck pain and may necessitate additional interventions. Due to loss of motion at the fused segment, the kinematics are changed at the levels above and below the fused segment. This has been shown in biomechanical studies to cause increase in intradiscal pressure and motion at the adjacent levels (Eck et al. 2002). It is still unclear whether this degeneration is a result of the natural progression seen with aging or a result of the change in biomechanical stresses seen with ACDF.

In contrast, biomechanical studies have reported that total disc replacement does not disrupt the kinematics at adjacent levels and allow for restoration of more normal load transfer (DiAngelo et al. 2003). Additional studies report that there are reduced stresses at adjacent levels in total disc replacement when compared to levels adjacent to a fusion (Pickett et al. 2005).

Indications/Contraindications

Cervical spondylosis is a common condition and can result in radiculopathy and myelopathy. Patients presenting with these symptoms should undergo appropriate work-up including radiographic evaluation and nonsurgical management. Radiographic evaluation, including MRI and CT imaging, can reveal single versus multilevel disease, presence of facet arthropathy, overall cervical spine alignment, kyphotic deformity, instability, and the location of compressive pathology (anterior, posterior, or both). The results of radiographic evaluation are crucial in determining whether a patient is an appropriate candidate for a total disc replacement.

In the setting of normal cervical alignment and mobility with failure of medical management, appropriate indications for total disc replacement include:

- Radiculopathy due to paracentral or central disc pathology or foraminal stenosis
- Myelopathy due to anterior compression by herniated disc

Contraindications for total disc replacement include:

- Significant multiple level degenerative disc disease (> two levels) with baseline motion abnormalities or advanced degeneration of the facet joints
- Abnormal global spinal alignment
- Cervical Instability (translation >3 mm and/or >11° rotational difference to that or either adjacent level)
- Active or prior discitis
- Osteoporosis (T-score < −1.5)
- Traumatic instability (ligament disruption or facet injury)
- Ossified posterior longitudinal ligament (OPLL) or the presence of bridging osteophytes
- Known allergy to implant materials

FDA-Approved Devices

Starting in 2006, eight cervical artificial disc devices have become available in the United States for one-level use, two of which, Mobi-C and Prestige LP, are approved for two-level use (Table 1). These devices vary in size, shape, materials, and articulating surfaces. They can be categorized based on biomechanical design, biomaterials, and type of fixation (Fig. 1) (Mummaneni and Haid 2004; Mummaneni et al. 2007).

Bryan Cervical Disc

Device Description

The Bryan cervical disc was developed in the early 1990s by neurosurgeon Vincent Bryan. The device is made of two titanium alloy shells with a polyurethane nucleus, which makes it a biarticulating contained bearing design. This is a non-modular disc. Fixation is achieved via milled vertebral end plates, and it allows end plate bony ingrowth through a porous end plate design (Fig. 2).

Table 1 Comparison of the eight FDA-approved artificial disc devices

Name	Design	Modular	Articulating method	Implant composition	Primary fixation	Manufacturer
Bryan	Metal-on-polyurethane, Biarticulating contained bearing	No	Biarticulating	Titanium, polyurethane core	Milled vertebral end plates	Medtronic
PCM	Metal-on-polyethylene Ball-and-socket	No	Uniarticulating	Cobalt - chromium, UHMWPE	Ridged, V-tooth design	NuVasive
ProDisc-C	Metal-on-polyethylene, ball-and-socket	Yes	Uniarticulating	Cobalt-chromium, UHMWPE	Central keel	DePuy Synthes (recently sold to Paradigm Spine)
Prestige ST	Metal-on-metal Ball-and-trough	No	Uniarticulating	Stainless steel	Locked vertebral body screws	Medtronic
Prestige LP	Metal composite, ball-and-trough	No	Uniarticulating	Titanium/ ceramic composite	Dual rails	Medtronic
Mobi-C	Metal-on-polyethylene, mobile core	Yes	Biarticulating	Cobalt - chromium, UHMWPE	Lateral self-retaining teeth	LDR
Secure-C	Metal-on-polyethylene, mobile core	No	Biarticulating	Cobalt - chromium, UHMWPE	Ridged central keel	Globus Medical
M6-C	Metal on polyurethane	No	Nonarticulating Compressible	Titanium/ Polyurethane UHMWPE	Triple fins	Spinal Kinetics

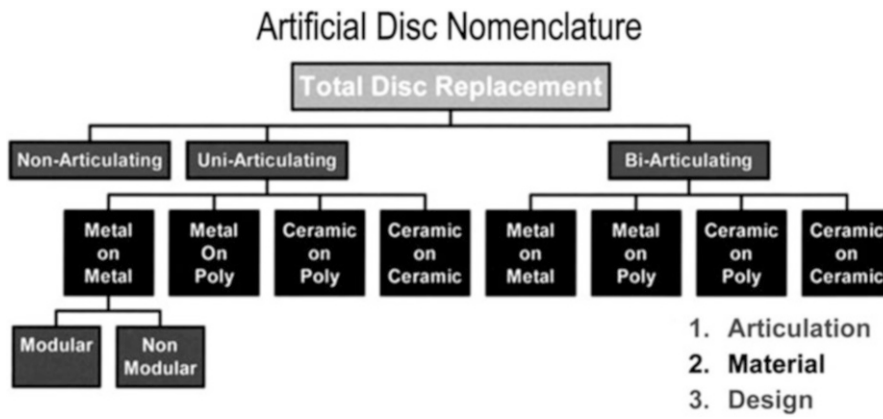

Fig. 1 Nomenclature for artificial disc implants based on design, articulation, and materials. (Permission for the reprint of figure obtained from Journal of Neurosurgery: Spine)

Outcomes

Recently, Goffin et al. reported results in 89 patients treated with the Bryan disc. Ten-year follow-up was available for 72 cases (81%). Maintenance or improvement of the neurological state was seen in 89% of patients. SF-36 patient reported scores improved significantly at all follow-up points. Mean angular motion of the

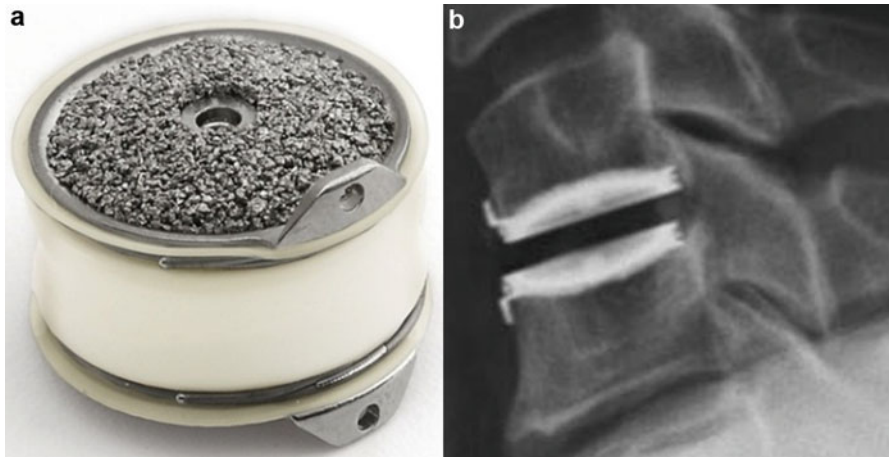

Fig. 2 Bryan artificial disc: (**a**) device; (**b**) lateral X-ray after implantation

prosthesis at 10-year follow-up was 8.6°. Mobility of the device, defined as >2° of angular motion, was reached in 81% of patients. During their study period, 21 patients (24%) developed new or recurrent radiculopathy or myelopathy; the majority of these patients were treated conservatively. Seven patients (8%) required 8 additional spine surgeries to treat persistent or recurrent symptoms. Of these, two patients (2%) were reoperated on at the index level, and five (6%) patients underwent surgery at an adjacent level (Goffin et al. 2003).

Heller et al. presented the results of a randomized controlled multicenter clinical study in 2009 with 242 patients in the investigational group (Bryan arthroplasty) and 221 patients in the control group (single-level ACDF). They showed statistically significant favorable results in the investigational group in various parameters like NDI, neck pain, and return to work and comparable results in other parameters like arm pain and SF 36 physical and mental components. At 24 months, overall success was achieved in 82.6% of the patients in the investigational group and 72.7% in the control group. This difference of 9.9% was statistically significant ($P = 0.010$), and a similar difference was noted at the 12-month follow-up interval ($P = 0.004$) (Heller et al. 2009).

Porous Coated Motion (PCM) Prosthesis

Device Description

The porous coated motion prosthesis is designed to have a metal-on-polyethylene articular surface. This device is a uniarticulating design, which is not modular. It is made up of cobalt-chromium-molybdenum alloy end plates with a TiCaP porous coating for bony ingrowth. Fixation is achieved with a central V-tooth design in a "press fit" fashion (Fig. 3).

Outcomes

In 2015, Philips et al. published the long-term outcomes of the FDA IDE prospective, randomized controlled trial, which compared the PCM prosthesis to anterior cervical discectomy and fusion. The total patient pool of 293 patients (163 PCM, 130 ACDF) was evaluated at 5-year follow-up, and 110 patients had 7-year follow-up. They reported that at 5-year follow-up, all patient-reported outcomes – neck and arm pain visual analogue scale score, neck disability index, and general health (36-Item Short Form Health Survey physical and mental component scores: physical component summary, mental component summary) – were significantly improved from baselines in both groups. Mean scores were

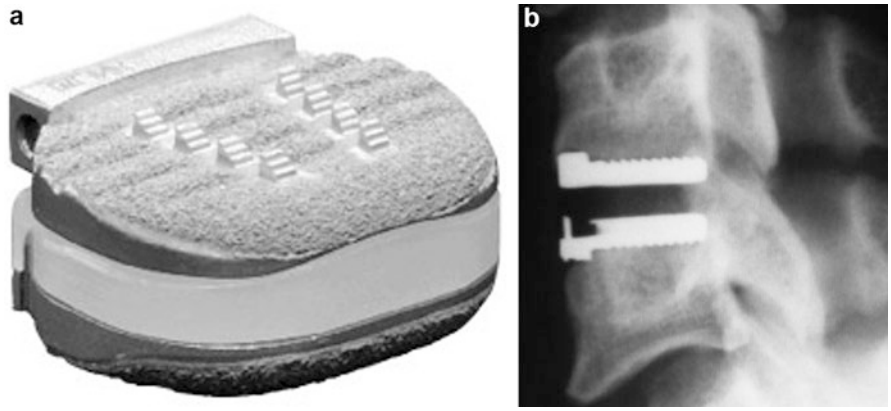

Fig. 3 Porous coated motion prosthesis: (**a**) device; (**b**) lateral X-ray after implantation

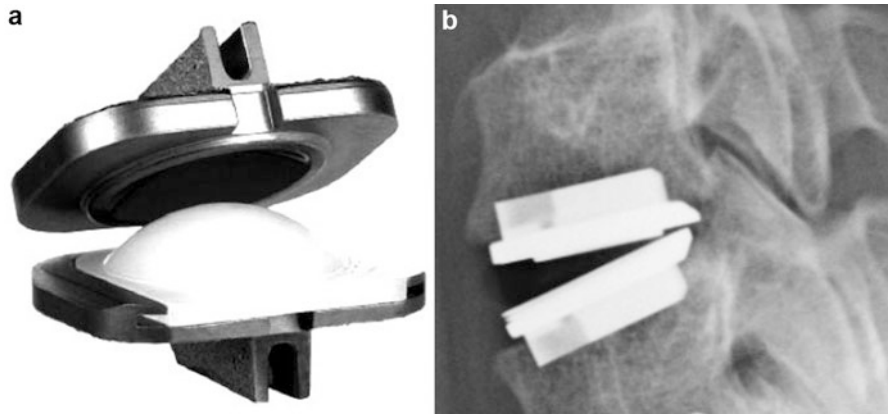

Fig. 4 ProDisc-C cervical disc: (**a**) device; (**b**) lateral X-ray after implantation

significantly better in the PCM group for neck disability index, neck pain, general health, and patient satisfaction. PCM patients trended toward fewer 2- to 7-year device-related serious adverse events and secondary surgical procedures. Adjacent-level degeneration was radiographically more frequent after ACDF and was the primary indication for the increase in late-term secondary surgical procedures after ACDF (Phillips et al. 2015).

ProDisc-C Cervical Disc

Device Description

The ProDisc-C cervical disc is similar in its design to the ProDisc lumbar disc prosthesis. It is a modular ball-and-socket type uniarticulating design. It consists of two cobalt-chromium-molybdenum end plates with an ultrahigh molecular weight polyethylene (UHMWPE) core. Fixation is achieved via a central keel (Fig. 4).

Outcomes

In 2016, Loumeau et al. published data from a randomized controlled trial comparing 7-year clinical outcomes of one-level symptomatic cervical disc disease following ProDisc-C total disc arthroplasty versus ACDF. A total of 22 patients were randomized to each arm of the trial. The authors reported that neck disability index (NDI) scores improved with the ProDisc-C greater than with ACDF. Total range of motion and neck and arm pain improved more in the ProDisc-C group

compared to the ACDF group. Patient satisfaction remained higher in the ProDisc-C group at 7 years. Six additional operations (two at the same level; four at an adjacent level) were performed in the ACDF group; however, no reoperations were performed in the ProDisc-C group. They concluded that ProDisc-C implants appear to be safe and effective for the treatment of cervical disc disease and had a lower reoperation rate than those patients treated with an ACDF (Loumeau et al. 2016).

Prestige ST Cervical Disc

Device Description

The Prestige ST was designed by Mr. Brian Cummins and was the first cervical total disc replacement to receive FDA approval in 2006. It is a stainless steel disc, which has a ball-and-trough design with biarticulating surfaces. It is secured to the vertebral body with screws. The superior and inferior surfaces, which contact the end plates, are treated to promote bone integration (Fig. 5).

Outcomes

A FDA IDE randomized controlled study reported by Mummaneni et al. compared cervical disc replacement using the Prestige ST device versus a single-level ACDF. Two-, 5-, and 7-year results have been published. Out of the 541 total patients in the study, 395 patients (212 Prestige ST, 183 ACDF) completed a 7-year follow-up. They found significantly improved NDI scores and neurological improvement scores in the investigational group as compared to the control group. Additionally, rates for subsequent surgical procedures that involved adjacent levels were significantly lower in the Prestige ST group (4.6% vs. 11.9%). They concluded that cervical disc arthroplasty using the Prestige ST cervical disc had the potential for preserving motion at the operated level while providing biomechanical stability and global neck mobility and could result in a reduction in adjacent segment degeneration (Burkus et al. 2014).

Prestige LP Artificial Disc

Device Description

The Prestige LP artificial disc has the same ball-and-trough articulation as the Prestige ST disc. However, the Prestige LP is made from a titanium ceramic composite material. It is anchored to the vertebral bodies via dual rails on the superior and inferior end plates. It also has a porous titanium spray coating to facilitate fixation and bone ingrowth (Fig. 6).

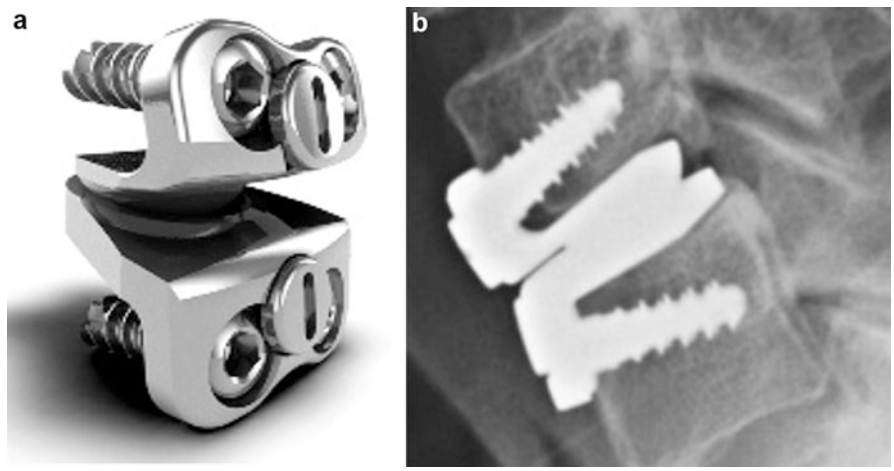

Fig. 5 Prestige ST cervical disc: (**a**) device; (**b**) lateral X-ray after implantation

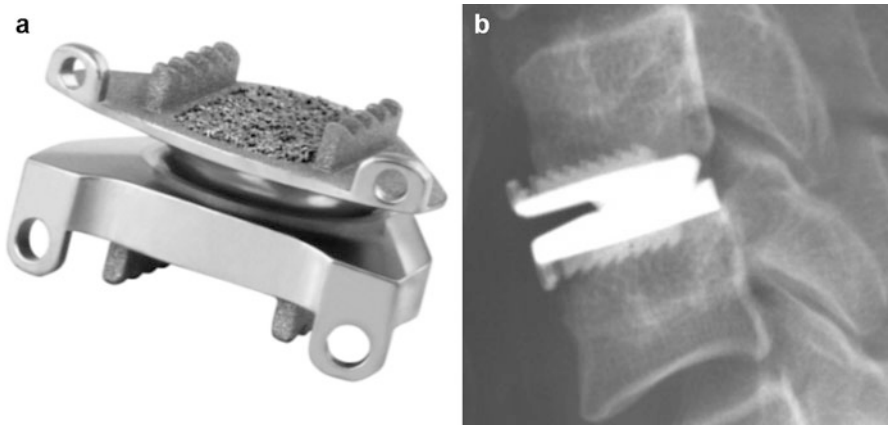

Fig. 6 Prestige LP cervical disc: (**a**) device; (**b**) lateral X-ray after implantation

Outcomes

The results of a randomized control study, investigating the Prestige LP device, were published by Gornet et al. in 2017. They assessed the long-term clinical safety and effectiveness in patients undergoing total disc replacement using the Prestige LP prosthesis to treat degenerative cervical spine disease at 2 adjacent levels compared with ACDF. The study was conducted at 30 centers in the United States with a total of 397 patients (209 Prestige LP, 188 ACDF). At 84 months, the Prestige LP demonstrated statistical superiority over fusion in overall success, NDI improvement, and neurological success. There was no statistically significant difference in the overall rate of implant-related or implant/surgical procedure-related adverse events up to 84 months. The Prestige LP group had fewer serious (Grade 3 or 4) implant- or implant/surgical procedure-related adverse events (3.2% vs. 7.2%,). Patients in the Prestige LP group also underwent statistically significantly fewer second surgical procedures at the index levels (4.2%) than the fusion group (14.7%). Angular range of motion at the superior- and inferior-treated levels on average was maintained in the Prestige LP group up to 84 months (Gornet et al. 2017).

Mobi-C Cervical Disc

Device Description

The Mobi-C cervical disc was first implanted in 2004. This device has a biarticulating design of metal plates articulating on a polyethylene modular core. It has lateral self-retaining teeth on the superior and inferior metal plates, which are pressed into the bone for fixation. The plates are coated with hydroxyapatite to enhance bone integration (Fig. 7).

Outcomes

Hisey et al. published their results in 2016 of a prospective, randomized, controlled study which was conducted as a FDA IDE trial across 23 centers with 245 patients randomized (2:1) to receive total disc replacement with Mobi-C cervical disc or ACDF. The 60-month follow-up rate was 85.5% for the Mobi-C group and 78.9% for the ACDF group. The composite overall success was 61.9% with Mobi-C vs. 52.2% with ACDF, demonstrating statistical non-inferiority. Improvements in NDI, VAS neck and arm pain, and SF-12 scores were similar between groups and were maintained from earlier follow-up through 60 months. There was no significant difference between Mobi-C and ACDF in adverse events or

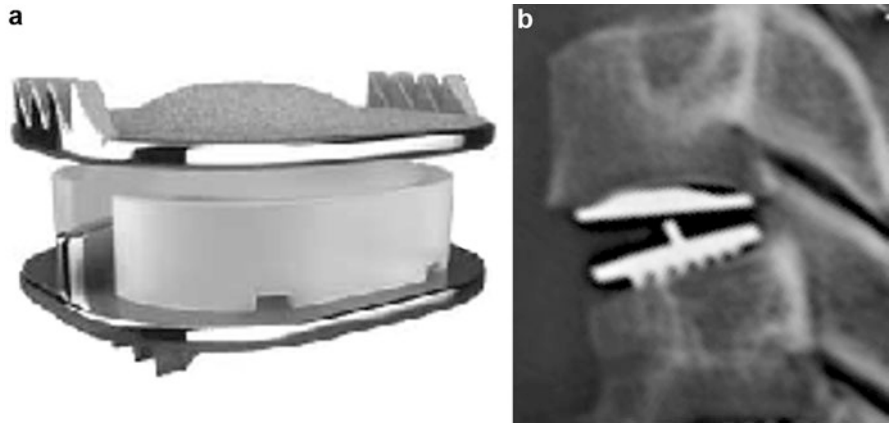

Fig. 7 Mobi-C cervical disc: (**a**) device; (**b**) lateral X-ray after implantation

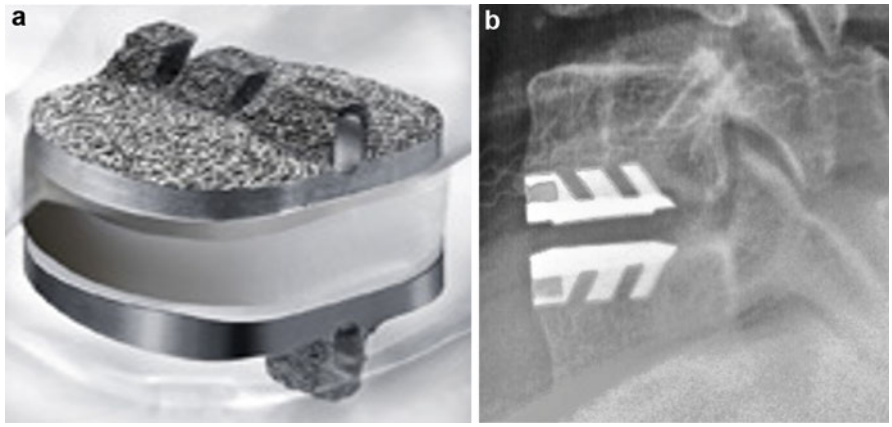

Fig. 8 Secure-C cervical disc: (**a**) device; (**b**) lateral X-ray after implantation

major complications. Range of motion was maintained with Mobi-C through 60 months. Device-related subsequent surgeries (Mobi-C 3.0%, ACDF 11.1%) and adjacent segment degeneration at the superior level (Mobi-C 37.1%, ACDF 54.7%) were significantly lower for Mobi-C cohort. They concluded that total disc replacement with Mobi-C is a viable alternative to single-level ACDF (Hisey et al. 2016).

Secure-C Cervical Disc

Device Description

The Secure-C device is a selectively constrained anterior articulating intervertebral device comprised of two end plates and a central core. The superior and inferior cobalt-chrome alloy end plates have multiple serrated keels for short-term fixation and titanium plasma spray coating on bone contacting surfaces for long-term bony ingrowth. The sliding central core is composed of ultrahigh molecular weight polyethylene, with a spherical superior interface (Fig. 8).

Outcomes

Vaccaro et al. published results of a prospective, multicenter, randomized controlled IDE trial to compare the clinical safety and effectiveness of the Secure-C device versus ACDF. A total of 380 patients from 18 investigational sites were randomized and evaluated. Overall, the study

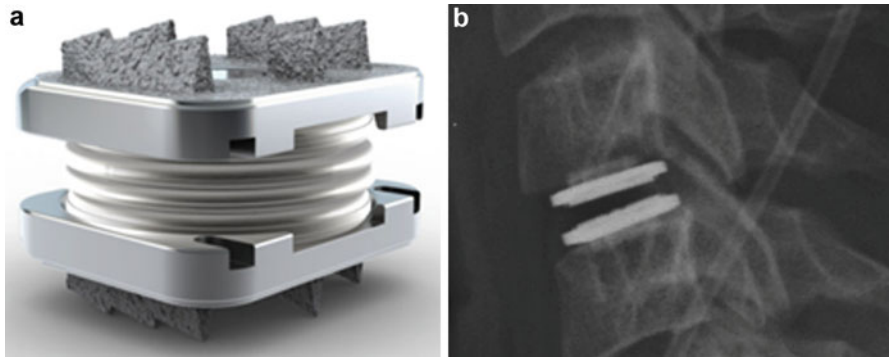

Fig. 9 M6-C artificial disc: (**a**) device; (**b**) lateral X-ray after implantation

demonstrated the statistical superiority of the Secure-C group compared with the ACDF group at 24 months. At 24 months, the Secure-C cohort demonstrated clinically significant improvement in pain and function in terms of NDI scores, VAS scores, and 36-Item Short Form Health Survey. At 24 months, the percentage of patients experiencing secondary surgical interventions at the index level was statistically lower for the Secure-C group (2.5%) than the ACDF group (9.7%). This type of disc has also proven to be a viable alternative to ACDF in appropriately selected patients (Vaccaro et al. 2013).

M6-C Artificial Cervical Disc

Device Description

The M6-C disc is an unconstrained disc with a polyethylene weave (designed to mimic the annulus fibrosus) which houses a compressible viscoelastic polyurethane core (designed to mimic the nucleus pulposus). The end plates are titanium with a plasma spray coating, and fixation is achieved with three rows of "fins" on the upper and lower end plates (Fig. 9).

Outcomes

Lauryssen et al. published results of a prospective, multicenter, non-controlled IDE pilot study to evaluate the clinical safety and effectiveness of the M6-C disc. A total of 30 patients from 3 investigational sites were evaluated and demonstrated significantly improved clinical outcomes (NDI, VAS neck and arm scores) compared to baseline at 2-year follow-up (Lauryssen et al. 2012).

Conclusion

Eight cervical artificial disc devices have been approved by the FDA dating back to 2006. These devices have a sound evidence basis as safe and viable alternatives to ACDF in properly selected patients. Patient selection is key to ensure appropriate patient outcomes as seen in these FDA IDE studies. Further long-term investigations will be necessary to ensure the longevity of these devices.

References

Burkus JK, Traynelis VC, Haid RW Jr et al (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

Cloward RB (2007) The anterior approach for removal of ruptured cervical disks. 1958. J Neurosurg Spine 6(5):496–511. https://doi.org/10.3171/spi.2007.6.5.496

Coric D, Nunley P, Guyer RD, Musante D, Carmody C, Gordon C, Lauryssen C, Ohnmeiss D, Boltes MO (2011) Prospective, randomized, multicenter study of cervical arthroplasty: 269 patients from the Kineflex®| C artificial disc IDE study with minimum two year follow-up. J Neurosurg-Spine 15:348–358

DiAngelo DJ, Roberston JT, Metcalf NH et al (2003) Biomechanical testing of an artificial cervical joint

and an anterior cervical plate. J Spinal Disord Tech 16(4):314–323

Dohler JR, Kahn MR, Hughes SP (1985) Instability of the cervical spine after anterior interbody fusion. A study on its incidence and clinical significance in 21 patients. Arch Orthop Trauma Surg 104(4):247–250

Eck JC, Humphreys SC, Lim TH et al (2002) Biomechanical study on the effect of cervical spine fusion on adjacent-level intradiscal pressure and segmental motion. Spine (Phila Pa 1976) 27(22):2431–2434. https://doi.org/10.1097/01.BRS.0000031261.66972.B1

Fuller DA, Kirkpatrick JS, Emery SE et al (1998) A kinematic study of the cervical spine before and after segmental arthrodesis. Spine (Phila Pa 1976) 23(15):1649–1656

Goffin J, Van Calenbergh F, van Loon J et al (2003) Intermediate follow-up after treatment of degenerative disc disease with the Bryan Cervical Disc Prosthesis: single-level and bi-level. Spine (Phila Pa 1976) 28(24): 2673–2678. https://doi.org/10.1097/01.BRS.0000099392.90849.AA

Gornet MF, Lanman TH, Burkus JK et al (2017) Cervical disc arthroplasty with the Prestige LP disc versus anterior cervical discectomy and fusion, at 2 levels: results of a prospective, multicenter randomized controlled clinical trial at 24 months. J Neurosurg Spine 26(6): 653–667. https://doi.org/10.3171/2016.10.SPINE16264

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 (Phila Pa 1976) 34(2):101–107. https://doi.org/10.1097/BRS.0b013e31818ee263

Hilibrand AS, Carlson GD, Palumbo MA et al (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 MS, Zigler JE, 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 10:10. https://doi.org/10.14444/3010

Loumeau TP, Darden BV, Kesman TJ et al (2016) A RCT comparing 7-year clinical outcomes of one level symptomatic cervical disc disease (SCDD) following ProDisc-C total disc arthroplasty (TDA) versus anterior cervical discectomy and fusion (ACDF). Eur Spine J 25 (7):2263–2270. https://doi.org/10.1007/s00586-016-4431-6

Lauryssen C, Coric D, Dimmig T, Musante D, Ohnmeiss DD, Stubbs HA (2012) Cervical total disc replacement using a novel compressible prosthesis: results from a prospective Food and Drug Administration-regulated feasibility study with 24-month follow-up. Int J Spine Surg 6:71–77. https://doi.org/10.1016/j.ijsp.2012.02.001

Mummaneni PV, Haid RW (2004) The future in the care of the cervical spine: interbody fusion and arthroplasty. Invited submission from the Joint Section Meeting on Disorders of the Spine and Peripheral Nerves, March 2004. J Neurosurg Spine 1(2):155–159. https://doi.org/10.3171/spi.2004.1.2.0155

Mummaneni PV, Burkus JK, Haid RW et al (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

Phillips FM, Geisler FH, Gilder KM et al (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 (Phila Pa 1976) 40(10):674–683. https://doi.org/10.1097/BRS.0000000000000869

Pickett GE, Rouleau JP, Duggal N (2005) Kinematic analysis of the cervical spine following implantation of an artificial cervical disc. Spine (Phila Pa 1976) 30(17):1949–1954. https://doi.org/10.1097/01.brs.0000176320.82079.ce

Smith GW, Robinson RA (1958) The treatment of certain cervical-spine disorders by anterior removal of the intervertebral disc and interbody fusion. J Bone Joint Surg Am 40-A(3):607–624

Vaccaro A, Beutler W, Peppelman W et al (2013) Clinical outcomes with selectively constrained SECURE-C cervical disc arthroplasty: two-year results from a prospective, randomized, controlled, multicenter investigational device exemption study. Spine (Phila Pa 1976) 38(26):2227–2239. https://doi.org/10.1097/BRS.0000000000000031