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Neurosurg Clin N Am 16 (2005) 609–619

NEUROSURGERY
CLINICS
OF NORTH AMERICA

General Considerations for Cervical Arthroplasty with Technique for Prodisc-C

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Anterior cervical discectomy and fusion (ACDF) has demonstrated excellent success in the alleviation of cervical radiculopathy and myelopathy in properly selected patients, with greater than 90% of patients clinically improved after surgery [1]. Anterior cervical discectomy without reconstruction alters the normal alignment and stability of the spine and leads to a high incidence of residual neck and shoulder pain [2,3]. This problem limits the overall effectiveness of the procedure. Concurrent fusion is accomplished by the insertion of bone graft (harvested from the patient's own hip or a cadaver or using a synthetic spacer) after the disc is removed to reapproximate disc height and promote solid fusion of the adjacent vertebrae. Arthrodesis and maintenance of spinal alignment are further aided with the application of anterior plating, especially for multilevel procedures, and fusion rates approach greater than 90% for single- and double-level procedures [4,5]. Despite its effectiveness, fusion of a normally mobile spinal segment is not an ideal reconstruction. Biomechanical studies demonstrate that fusion results in abnormal loading of adjacent discs and facets and places additional stress on the intervertebral joints above and below the fusion [6]. Over time, radiographic and clinical deterioration at adjacent disc levels after fusion has been reported to occur at 2% to 3% annually, and an estimated 7% to 15% of patients with prior cervical fusions require another operation at an adjacent level [7]. Although initially interpreted as evidence of a natural progression of degenerative spine disease, many believe that fusion alters spinal biomechanics sufficiently enough to exacerbate adjacent level degeneration [5,8–10].

This concern over adjacent level degeneration in patients treated with ACDF has prompted the evolution of motion-sparing spinal arthroplasty. Joint arthroplasty has been extremely successful in providing excellent motion preservation and functional mobility while minimizing adjacent joint stress [11,12]. For example, knee arthrodesis used as a treatment for debilitating knee degeneration was associated with accelerated rates of hip, lower back, and ankle joint degeneration. Recent technologic advances and improved understanding of spinal biomechanics and bone biology have allowed for the development of several artificial cervical discs, which are currently used in clinical practice in Europe, Australia, Asia, and South America and are under investigational use in the United States (at the time of this publication). The goals of cervical arthroplasty are to (1) maintain or restore intervertebral height and spinal balance, (2) maintain or restore intervertebral mobility, and (3) avoid adjacent level degeneration long term. Although still an "infant" technology, certain general considerations are important to understand as this field begins to take flight. These

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doi:10.1016/j.nec.2005.07.001

include the current clinical indications and contraindications for cervical spinal arthroplasty, differences in current artificial disc design, awareness of potential complications and limitations, and its economic impact on our health care system.

Patient selection

Indications

As of 2005, more than 6000 artificial cervical discs are estimated to have been implanted worldwide, predominantly outside the United States [13]. In the United States, artificial cervical disc implants are currently not approved by the US Food and Drug Administration (FDA) and surgery is performed under investigational use exemption status for institutional trials. Therefore, clinical indications for the implantation of artificial cervical discs are certain to derive from the inclusion criteria for these investigational use studies. In general, any patient who is a candidate for single- or double-level ACDF surgery with radiculopathy or myelopathy is also a cervical arthroplasty candidate (Box 1) [5,14,15]. It is important to recognize that most patients with new-onset neck and arm pain and findings consistent with cervical disc herniation improve within 6 weeks with conservative measures. These include anti-inflammatory and painkiller medications, physical therapy, and neck bracing, and a minimum waiting period of 6 weeks with maximal conservative therapy should be instituted. Patients with signs of acute or progressive myelopathy and weakness with confirmed spinal cord compression should undergo immediate decompression without waiting the 6-week period. No distinction is made between "hard" and "soft" discs, and clinical symptoms must correspond to radiographic findings. Currently, trials in the United States are for a one-disc level between C3 and C7. Multilevel surgery has been performed in select cases with compassionate exemption. It is important to recognize that the international experience encompasses a much broader set of clinical indications, allowing for up to four-level arthroplasty and use in acute settings.

Box 1. Clinical indications based on inclusion criteria for cervical arthroplasty trials and clinical contraindications based on exclusion criteria for cervical arthroplasty trials

Inclusion criteria for cervical arthroplasty trials

1. Presence of radiculopathy and/or myelopathy attributable to cervical disc degeneration at one to two levels
2. Symptoms and findings referable between the C3 and C7 levels
3. Presence or absence of neck pain
4. Failure of conservative treatment (minimum of 6 weeks)
5. Radiographic confirmation of spinal cord and/or nerve root compression corresponding to symptoms

Exclusion criteria for cervical arthroplasty trials

1. Prior cervical laminectomy or laminoplasty and or prior cervical fusion surgery
2. Acute traumatic fracture and/or disc herniation
3. Structural instability and/or kyphosis of cervical spine
4. Predominant posterior stenosis
5. Osteoporosis and related metabolic bone disease
6. Chronic steroid use
7. Insulin-dependent diabetes mellitus
8. Axial neck pain only
9. Diagnosis of ankylosing spondylitis, ossified posterior longitudinal ligament, or diffuse idiopathic skeletal hyperostosis
10. Extreme obesity
11. Inability to perform and adequately visualize arthroplasty level during surgery

Contraindications

Contraindications for cervical arthroplasty are based on exclusion criteria for trials in the United States. These are designed to maximize the success of artificial disc implantation in ongoing prospective trials, and thus extend beyond the contraindications for ACDF (see Box 1). Although some studies have excluded patients with prior cervical fusion, the safety of artificial disc implantation adjacent to prior ACDF is well accepted [16,17]. Prior posterior laminectomy without fusion,

however, is considered a risk factor for structural instability if an artificial disc were to be implanted. Patients with acute fractures and traumatic disc herniations should not undergo decompression and reconstruction with artificial discs, as is the case for patients with ankylosing spondylitis, an ossified posterior longitudinal ligament, and diffuse idiopathic skeletal hyperostosis (DISH). Osteoporosis (and related metabolic bone diseases), chronic steroid use, insulin-dependent diabetes mellitus, pregnancy, and morbid obesity are all currently contraindications for enrollment in cervical arthroplasty trials. Significant cervical anatomic deformity, including moderate to advanced spondylosis or radiographic subluxation greater than 2 mm or 11° of angulation at the affected vertebral level, is also considered a contraindication for cervical arthroplasty. Patients must not have any question of posterior column instability before surgery. The exclusion of patients with pending litigation or workman's compensation claims relating to spinal injury is frequently encountered in United States trials. This specific exclusion criterion is designed to prevent bias in outcomes for the purposes of these studies and does not represent a true surgical contraindication. Also, patients with axial neck pain alone are excluded from most prospective trials for cervical arthroplasty, although they obviously represent a patient population that may benefit from cervical arthrodesis or arthroplasty. Finally, because of technical considerations during the implantation of these devices, the level of arthroplasty must be clearly visualized during lateral and anterior-posterior (AP) fluoroscopy in surgery. The inability to visualize the level of interest adequately is a strict technical contraindication for cervical arthroplasty, which may be overcome with future advances.

The previous list of clinical indications and contraindications is obviously a "work in progress." It is important to remember that patients with preserved cervical lordosis and multilevel disc herniations may be candidates for cervical laminectomy without fusion, laminoplasty, or cervical disc arthroplasty. Patients with mild loss of cervical lordosis may represent the group with the highest potential benefit from motion-preserving arthroplasty, whereas patients with fixed kyphosis may be poor candidates for artificial disc surgery. As experience with cervical arthroplasty increases and results from ongoing trials are analyzed, our understanding of ideal candidates for these devices is undoubtedly going to expand.

Disc design

There are currently several artificial cervical discs under the process of evaluation in FDA-approved United States clinical trials (Fig. 1). Each has its own unique features based on the type of material construction, joint design and kinematics, and fixation to host bone.

Materials

In general, artificial joints can use a combination of metal, polymer, and ceramic in their construction [18]. Metal-on-metal joints were the earliest to be designed but were considered "high-friction" because of early limitations in the manufacturing process. These issues led to the generation of metallic wear debris, which may cause unwanted inflammatory responses or systemic toxicity [19]. Metal-on-polymer discs have been favored because of their "low-friction" biomechanics but still have debris particles that have a theoretic potential for undesired toxicity or inflammation [20,21]. So far, studies show an extremely low risk of adverse events from these materials in cervical arthroplasty [22,23]. Ceramics provide additional friction reduction and may become increasingly popular in conjunction with polymers to eliminate metallic artifact during imaging follow-up. Ceramic surfaces have low friction and generate the least amount of particulate debris. This material has a potential to fracture and fragment if loaded inappropriately, however. Ceramics are also susceptible to failure by edge loading of the end plate and the interface of one articulating surface to the other. Although not currently available, discs may also be modular (having replaceable components), aiding in future revision, or nonmodular.

Joint design and kinematics

Of paramount importance in the design of spinal artificial discs is consideration of biomechanical joint constraint. A natural cervical disc confers limited motion (constraint) in six vectors: flexion, extension, rotation, compression, translation, and distraction. Although a disc with a high degree of mobility seems desirable, in fact, biomechanical studies have shown that a certain amount of constraint is beneficial in preventing

					
Tradename	Prestige II	Bryan	PCM	ProDisc-C	Cervicore
Manufacturer/ Distributor	Medtronic Sofamor-Danek	Medtronic Sofamor-Danek	Cervitech	Synthes Spine Solutions	Stryker Spine Care
Design	Metal-Metal Ball-socket	Metal-Polyurethane Cores	Metal-UHMWPE Load Bearing	Metal-Polyethelene Ball-socket	Metal-Metal Ball-socket
US FDA IDE Status	Initiated 2002 Expected Release 2006	Initiated 2002 Expected Release 2007?	Initiated 2005 Expected Release 2008?	Initiated 2002-3 Expected Release 2007?	Under study development

Fig. 1. Commercially marketed cervical artificial discs currently under clinical investigation in the United States. IDE, investigational device exemption. (Courtesy of Medtronic Sofamor Danek, Inc, Cervitech, Synthes Spine, and Stryker, with permission. Bryan Cervical Disc System incorporates technology developed by Gary K. Michelson, MD. CAUTION: Investigational devices limited by United States Federal Law to Investigational use.)

the transmission of excessive forces to adjacent joints, especially to posterior facets [8,24–28].

Modern first-generation cervical discs were designed as basic metal-on-metal ball-in-socket joints (Prestige Cervical Disc; Medtronic Sofamor Danek, Memphis, Tennessee and Prodisc-C; Synthes Spine Solutions, Paoli, Pennsylvania), which allowed for semiconstrained flexion, extension, rotation, and translation as well as constrained compression and unconstrained distraction [16,17,29]. The desire to provide cushioning and improved translation led to second-generation discs made of metal and polymer combinations (Bryan Cervical Disc; Medtronic Sofamor Danek and Porous Coated Motion [PCM]; Cervitech, Rockaway, New Jersey). The Bryan disc [30–32] is designed as two polyurethane cores articulating between titanium shells encased in an elastic sheath, whereas the PCM disc [15,33] is made of a large-radius, ultrahigh-molecular-weight, polyethylene (UHMWPE) mobile core attached to titanium end plates. These types of joints are considered entirely semiconstrained, allowing for limited flexion, extension, rotation, translation, and compression (shock absorption) but little limit on distraction. The encapsulating elastic covers of the Bryan disc and the UHMWPE of the PCM disc are primarily designed for wear particle containment and actually allow for more distraction than normal. Third-generation artificial discs should better approximate natural disc architecture and incorporate components mimicking the nucleus pulposus and disc annulus, resulting in balanced semiconstrained motion in all six vectors [34].

Fixation to host bone

Proper fixation is critical to prevent implant migration and ensure joint stability during active motion. Ideally, disc implants would be fixed to the end plates alone and avoid involvement of the vertebral bodies. To achieve this, artificial discs have been designed with midline keels, or fins (ProDisc-C) [15], or contoured surfaces [33,35] (Bryan and PCM discs), which confer immediate end plate fixation. In any artificial disc procedure, precise localization and identification of the midline are required for proper positioning and insertion, because proper balance of the disc is required to maintain normal centers of rotation and prevent asymmetric neuroforaminal impingement. In addition, contoured surfaces can be precisely milled into the end plate surfaces to give a "perfect fit" on placement. Long-term fixation relies on bony ingrowth along the implant end plates, which is aided with porous ingrowth surfaces. An alternative method for disc fixation uses vertebral body screws similar to cervical plating systems. These designs may be beneficial in patients whose end plates may be weak, compromised, or unreliable. Early designs were fairly bulky and made multilevel application difficult or impossible. Next-generation designs

have offset screw fixation that allows for multilevel implantation.

Complications and limitations

Because the goal of cervical arthroplasty is to recapitulate balanced cervical motion, improper alignment, implant migration, or subsidence cannot be tolerated. The risk and rate of structural device failure are currently unknown, but most reported studies have low rates [10,17,30,32,33,36–41]. Proper placement of artificial discs with the aid of intraoperative fluoroscopy or image-guided systems can ensure proper sagittal and coronal alignment and help to prevent subsidence and graft migration. Anatomic studies have shown unique features of cervical vertebrae that differ from lumbar vertebrae. Most striking is the presence of the uncinate processes along the lateral extent of the superior end plates of the cervical spine. The uncovertebral joint confers additional stability in lateral bending and can prevent migration of the implant. Preservation of the posterior longitudinal ligament may also confer increased stability and prevent posterior migration. Cortical bone density is greatest at the outer footprint of the end plates, and proper sizing of cervical implants, along with preservation of the end plates, can ensure maximal dispersion of contact forces throughout the bony end plate.

Spondylotic bridging

Spondylotic bridging is the result of excessive bone growth at the implant site, which can constrain its motion [42]. Spondylotic bridging seems to occur most often with the Bryan implant [30,43,44]. This problem has been attributed to injury to the longus colli or to bone debris generated during the milling process [43]. Osteogenic promoters, such as bone morphogenic proteins, should not be applied to the surgical area during arthroplasty procedures. Some authors report the early use of nonsteroidal anti-inflammatory drugs to prevent heterotopic ossification and bridging, but no conclusive evidence exists to support their routine use [43,45]. Certain conditions likely predispose to spondylotic bridging, such as ankylosing spondylitis and DISH; thus, artificial discs should be used with extreme caution in these patients.

Device fatigue

A unique problem with motion-preserving arthroplasty is the potential for wear of the artificial joint and consequent reaction or rejection of the wear particles. This risk is higher in joints that bear higher loads, such as the hip, knee, and lumbar spine. The relatively small load of the cervical spine likely protects cervical artificial discs from excessive mechanical wear. Unfortunately, the actual ''life expectancy'' for an artificial disc after implantation in the human spine is unknown. Younger patients must be informed of the possibility of prosthetic failure within their lifetimes, requiring further surgery.

Cervicothoracic junction

So far, artificial cervical discs have only been studied at C3 to C7 intervertebral levels. Although some case series do report C7 to T1 arthroplasty among their patient cohorts, the cervicothoracic junction should be viewed with caution [46]. Although preservation of motion at the C7 to T1 level seems most appealing, it also represents a junctional transition from the highly mobile cervical spine to the relatively immobile thoracic spine. No case reports have been published for the C2 to C3 level, and arthroplasty here should be also be undertaken with extreme caution.

Prior fusion or surgery

Perhaps the most appealing feature of cervical arthroplasty may lie in the possibility of implanting a motion-preserving disc at a level adjacent to a segment already fused. Repeat surgery for patients with prior ACDF and subsequent development of adjacent level disease may now be undertaken with disc replacement rather than extension of fusion [17,47]. Unfortunately, not all patients with cervical radiculopathy and myelopathy have had anterior surgery alone in the past. Adjacent degeneration after posterior decompression and fusion is currently not amenable to artificial disc implantation. In the near future, development of posterior motion-preserving technology may provide the needed supplement to allow for ''circumferential motion preservation arthroplasty.'' Also, patients with severe multilevel cervical spondylosis with focal posterior compression requiring laminectomy and posterior fusion may benefit from combination fusion with adjacent arthroplasty to limit the total number of segments being fused.

Economic impact

Approximately 150,000 ACDF procedures are performed annually in the United States, encompassing more than 200,000 intervertebral segments [48]. Industry estimates indicate that more than $20 billion is spent treating neck pain and radiculopathy annually. The average cost of single- or double-level ACDF is estimated at $10,000 to $15,000, including the cost of implants, operative costs, surgeon's fees, and hospital time. Currently, artificial cervical discs are not approved by the FDA in the United States and are used as investigational devices only. As such, the average implant cost for a cervical total disc replacement is estimated to range from $5000 to $7000 [13]. Reimbursement schedules for Medicare and most large insurance carriers pay for cervical arthroplasty at an amount equivalent to a standard ACDF per level, despite arthroplasty surgery requiring longer operative times, costing more per implant, and demanding increased technical skills compared with ACDF surgery. Ongoing negotiations with public and private insurers regarding reimbursement for spinal arthroplasty are undoubtedly going to have an impact on its use and development as a viable alternative to spinal arthrodesis. Industry estimates place the total cost of single-level arthroplasty to reach as high as $50,000 [49]. Additionally, growth in spinal arthroplasty (lumbar and cervical) is expected to increase 19% by 2008 to 2010, representing a $5 billion market [49,50].

Because ACDF has been so successful at functional recovery and pain relief in patients, it is currently unclear how much of an impact cervical arthroplasty is likely to have compared with ACDF on economic losses from immediate and short-term opportunity costs and disability, especially for single-level surgery. The true impact of cervical arthroplasty may lie in its ability to prevent adjacent segment degeneration and obviate the need for medical treatment, diagnosis, and repeat surgery in the 7% to 15% of patients with ACDF who require future surgery. Additionally, the success of multilevel arthroplasty may obviate the need for circumferential fusion, and the costs associated with anterior and posterior surgery in patients requiring surgery at two, three, or four or more levels. Currently, no reliable estimates for these "savings" exist, and adjacent level degeneration may still occur at reduced rates despite motion preservation [13]. Nevertheless, conservative opinion among industry and market analysts predicts that spinal arthroplasty can capture up to 40% of the current market of spinal fusion within 5 years of its release.

Summary of current trials in cervical arthroplasty

There are currently several prospective, randomized, controlled trials using a variety of implants underway in the United States and abroad. The current literature predominantly comprises pilot and cohort studies with limited 1 to 2 years of follow-up (Table 1). The Prestige disc was the earliest to be implanted, and 4-year follow-up data became available in 2004 [51]. These data, along with the findings of other published reports, provide evidence that cervical arthroplasty is at least as effective as standard ACDF for one or two levels, while preserving motion. In studies with 1 to 2 years of radiographic follow-up, range of motion at the level of arthroplasty was preserved between 6° and 11° in flexion and extension. Although only one study has compared arthroplasty with fusion [52], pain scores, quality-of-life assessments, and functional outcome scores all seem to have improved significantly after arthroplasty to a degree at least commensurate to arthrodesis. Reports of implant complications have been low and suggest that arthroplasty implants do not confer any greater risk compared with arthrodesis implants. Preliminary evidence indicates that cervical arthroplasty is likely to have equivalent clinical outcomes to those of fusion surgery but with preservation of motion.

Future directions

Motion-preserving spinal arthroplasty is a triumph of modern biomechanics, material sciences, and surgical technique. The ability to remove entire intervertebral discs and replace them with prostheses that preserve height and alignment as well as motion and stability, all the while alleviating the pain and spinal cord compression, is the result of nearly 50 years of progress in joint arthroplasty, which many thought impossible. The results of ongoing trials for cervical discs are eagerly anticipated. Although the clear benefit or danger of artificial cervical discs is still unknown, they are already fundamentally changing the field of cervical spine surgery and are undoubtedly going to establish their place in the armamentarium for spinal surgeons.

Table 1
Summary of published cervical arthroplasty studies

Cervical arthroplasty study	Trial design	No. patients	No. implants	Follow-up	Outcome			Complications
					ROM	VAS	QOL	
Prestige disc								
Cummins et al, 1998 [16]	Pilot	20[a]	22	2.4 years average	Preserved	N/A	Improved	25%, 1 explanted device
Wigfield et al, 2002 [17]	Pilot	15[a]	15	2 years	6°	Improved	Improved	2 fractured screws, no explants
Robertson and Metcalf, 2004 [51]	Pilot	14[a]	14	4 years	6°	Improved	Improved	None reported
Robertson et al, 2002 [52]	PRCT	27	27	2 years	?	Improved[b]	Improved[b]	None reported
Bryan disc								
Bryan, 2002 [30]	Pilot	46	46	1 year	8°	N/A	Improved	1 reoperation, no explants
Bryan, 2002 (two levels) [30]	Pilot	9	18	2 years	11°	N/A	Improved	None reported
Duggal et al, 2004 [26]	Cohort	26	30	1 year	Preserved	Improved	Improved	None reported
Sekhon 2004 [45]	Pilot	11	15	1.5 years	Preserved	Improved	Improved	None reported
Pickett et al, 2004 [39]	Cohort	14	15	6 months	8°	N/A	Improved	Results show postoperative kyphosis at implant level common but cervical alignment preserved
Goffin et al, 2003 [37]	PMT	103	103	1–2 years	9°	Improved	Improved	3 reoperations, no device failure
Goffin et al, 2003 (two level) [37]	PMT	43	86	1 year	7°	Improved	Improved	4 reoperations, no device failure
Lafuente et al, 2005 [32]	Cohort	46	46	1 year	N/A	Improved	Improved	2 reoperations for explant
PCM disc								
Pimenta et al, 2004 [33]	Pilot	52	81	1 year	Improved	Improved	Improved	1 migration, 1 heterotopic ossification
ProDisc-C								
Bertagnoli et al, 2005 [36]	Cohort	16	20	1 year	12°	Improved	Improved	No device complications

Abbreviations: N/A, not applicable; QOL, quality-of-life rating based on the Short Form 36, Oswestry Disability Index, or Neck Disability Index; ROM, range of motion at level of implants after surgery; VAS, visual analogue scale used before surgery and at the end of follow-up; PMT, prospective multicenter trial; PRCT, prospective, randomized, controlled trial.

[a] All patients had prior cervical fusion surgery and received arthroplasty surgery at an adjacent level.

[b] Improvement observed compared to both preoperative status and with control group of 27 patients with ACDF.

Prodisc-C: An Introduction

The Prodisc-C is modeled directly from its older sibling, the lumbar Prodisc. It is designed as a ball-socket joint; with cobalt-chromium alloy endplates and an ultra-high molecular weight polyethylene inlay forming the articulating joint. The Prodisc-C is considered constrained in compression, unconstrained in distraction and rotation, and semi-constrained in flexion, extension, and lateral bending. Cadaveric biomechanical studies have demonstrated maintenance of near-physiologic range of motion under loading conditions and coupled motion [8,24]. Recent review

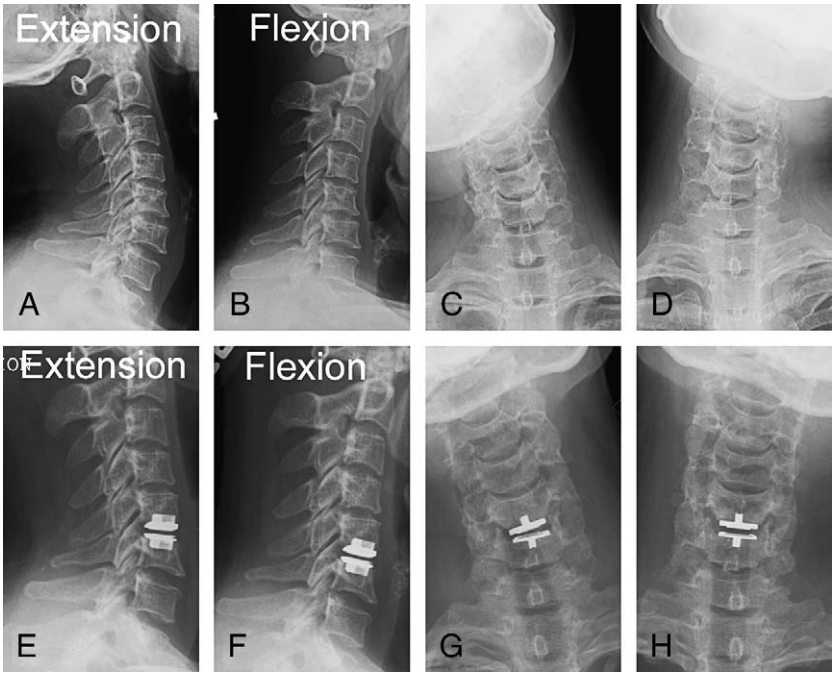

Fig. 2. Pre-operative cervical spine radiographs in (*A*) extension, (*B*) flexion, (*C*) right lateral bending, and (*D*) left lateral bending. Cervical spine radiographs in the same patient following Prodisc-C arthroplasty at C5-6 in (*E*) extension, (*F*) flexion, (*G*) right lateral bending, and (*H*) left lateral bending.

of 80 patients enrolled in 3 separate randomized clinical trials in Europe and the United States indicate excellent 6 and 12 month results, with equivalent relief of pain and improvement in function (based on visual analog scale, ODI, NDI, SF-36) compared to ACDF [53–55]. Additionally, Prodisc-C preserved noticeable range of motion in flexion and extension, without an increase in morbidity or complications. Currently, Prodisc-C is under investigation for FDA approval for single-level implantation (Fig. 2), but multilevel implantation has been successfully performed outside the United States (Fig. 3). So far, only 1 spontaneous fusion from heterotopic

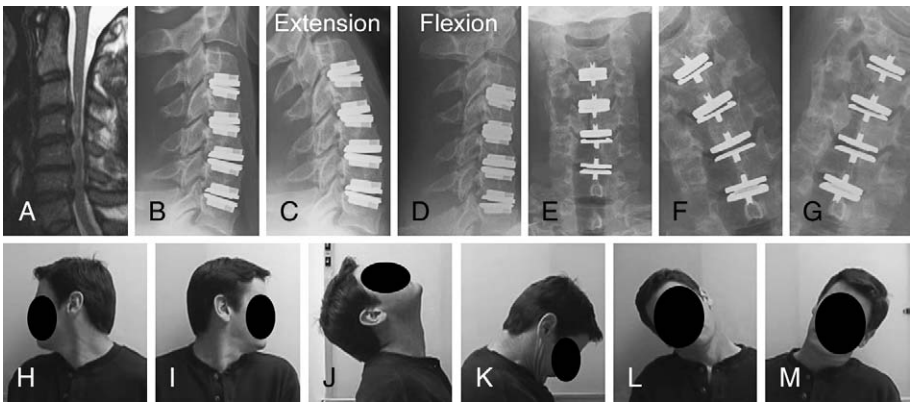

Fig. 3. (*A*) Pre-operative sagital T2-weighted MRI demonstrating significant disk herniations at C3-4, C4-5, C5-6, and C6-7. Post-operative cervical spine radiographs following 4-level Prodisc-C arthroplasty in (*B, E*) neutral position, (*C*) extension, (*D*) flexion, (*F*) right lateral bending, and (*G*) left lateral bending. Video snapshots of the same patient at 6 month follow up showing excellent range of motion in (*H*) right rotation, (*I*) left rotation, (*J*) extension, (*K*) flexion, (*L*) right lateral bending, and (*M*) left lateral bending.

ossification has occurred in the cited literature with Prodisc-C [53].

Prodisc-C: Surgical Technique

Patient positioning

Standard supine positioning for anterior approach to the cervical spine is used. The head is kept in neutral rotation to prevent malrotation of the prosthesis. A radiolucent table to allow fluoroscopic imaging of the spinal level in the anterior/posterior and lateral planes is mandatory.

Surgical procedure

The cervical spine is exposed through a right or left sided Smith-Robinson approach. The medial longus colli is mobilized around the affected segment and self-retaining retractors are placed to allow exposure of the disc space and the uncovertebral joints. Anterior-posterior (AP) fluoroscopy is used to locate the midline of the vertebral body, which is marked with a sharp osteotome (Fig. 4). The anterior annulus is excised and micro-curets are used to remove the cartilaginous endplates and disc material back to the posterior osteophyte or posterior longitudinal ligament. A starting awl is used to place Caspar-type distraction pins in the vertebral bodies in the midline (for single level application) or just offset from the midline (for multilevel application to prevent the formation of stress risers in the bone). The pins are also placed a sufficient distance from the interbody space to minimize the chance of impingement with the keel of the prosthesis (see Fig. 4). An interbody distractor is then placed and gradual and gentle interbody distraction is achieved. The exposure is maintained with

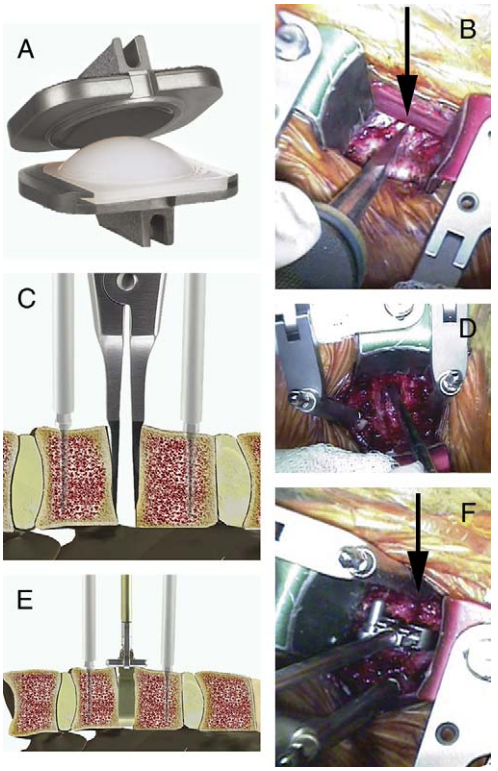

Fig. 4. (*A*) Prodisc-C artificial cervical disk implant. Intraoperative photos demonstrating (*B*) marking of the radiographically confirmed midline with a sharp osteotome (*arrow, midline*), (*D*) in situ vertebral distraction, and (*F*) insertion of sizing trial implant (*arrow, midline bone cut*). Schematic diagram showing (*C*) additional intervertebral distraction using a vertebral body spreader and (*E*) proper placement of the sizing trial implant.

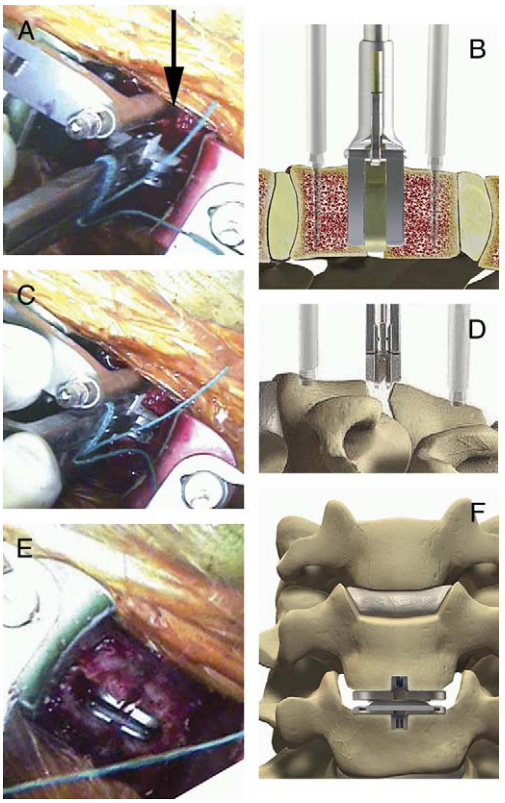

Fig. 5. (*A, C*) Implantation of the Prodisc-C artificial disk (*arrow, midline bone cut*), and (*E*) final position of implant in situ. Schematic diagrams showing (*B*) proper position of the keel cutter instrument with the trial implant, (*D*) Prodisc-C insertion, and (*F*) final position of the implant.

a vertebral body retainer. This allows excellent visualization of the endplates and the posterior interbody space. The remainder of the cartilaginous endplate and posterior osteophytes are removed and decompression of the central spinal canal and neural foramen are carried out with standard techniques. Removal of the bony endplates is avoided if at all possible to minimize the chance of implant subsidence. After the decompression is complete, trial implants are placed in the interbody space and examined under fluoroscopy to verify appropriate sizing in terms of implant depth, height, and width (see Fig. 4). Optimal implant height is determined under lateral fluoroscopy using the adjacent disc spaces as a guide, avoiding over-distraction of the interbody space. Over-distraction may lead to nerve root stretch, facet joint overload, and/or loss of motion. Once the optimal trial is selected, a keel cutter is placed over the chosen trial and the slot for the keel of the prosthesis is created in the vertebral bodies in the midline. A box osteotome is used to complete the bony cut for the implant keel (Fig. 5). After clearing the keel slot of any residual bony debris, the prosthesis is gently impacted into place as a single unit using fluoroscopy with the polyethylene dome pointing caudally (see Fig. 5). The incision is then closed in standard fashion.

Aftercare

Patients are placed in a soft cervical collar for comfort. Postural stabilization of the neck and physical therapy is instituted at 2–3 weeks post-op. Currently, radiographic follow-up is performed post-op and at 3, 6, and 12 month intervals and yearly thereafter.

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