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Derleme

Cervical Disc Arthroplasty: An Overview of Past, Present and Future

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Purpose of review: The present article reviews the most recent research into the rationale, patient selection, clinical results and complication profile of cervical arthroplasty.
Recent findings: Recent results of prospective randomized control trials comparing cervical disc replacement and anterior fusion have demonstrated safety as well as equal or superior clinical results. In vivo kinematic studies have suggested decreased rates of adjacent segment disease following disc replacement. Increasingly, more studies are examining the complication profile and emerging contra-indications for cervical disc replacement.
Summary: Cervical arthroplasty is a promising technique in that is undergoing rapid refinement and development. Further long-term data is eagerly awaited before the role in prevention of adjacent segment disease can be proven.

Key words: Cervical arthroplasty, complications, artificial cervical disc, kinematics, clinical outcomes, kyphosis

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Servikal Disk Artroplastisi: Geçmişim, Şimdi ve Gelecek

Derlemenin amacı: Bu makale servikal artroplastinin gerekçesi, hasta seçimi, klinik sonuçları ve komplikasyon profiline ilişkin en güncel araştırmaları gözden geçirmektedir.
Güncel bulgular: Servikal disk replasmanı ve anterior füzyonu karşılaştıran prospektif randomize kontrollü çalışmaların güncel sonuçları eşdeğer güvenlilik veya üstün klinik sonuçlar elde edildiğini göstermiştir. In vivo kinematik çalışmalar disk replasmanı sonrasında komşu segment hastalığı oranlarında azalma olduğunu ileri sürmüştür. Giderek artan sayıda çalışma disk replasman tedavisinin komplikasyon profili ve ortaya çıkan kontrendikasyonları incelemektedir.
Özet: Servikal artroplasti hızlı gelişme ve iyileştirmelerden geçmekte olduğu için servikal artroplasti umut vadeden bir tekniktir. Komşu segment hastalığını önlemedeki rolünü kanıtlayabilmek için daha fazla uzun süreli veriler hevesle beklenmektedir.

Anahtar kelimeler: Servikal artroplasti, komplikasyonlar, yapay servikal disk, kinematik, klinik sonuçlar, kifoz

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Anterior cervical discectomy and fusion (ACDF) is one of the most commonly performed spinal surgeries for the treatment of cervical radiculopathy, myelopathy and neck pain [1,2]. Although it is an extremely effective procedure for alleviating clinical symptoms, there are significant disadvantages both immediate and long term, which lead to a significant incidence of reoperation for adjacent segment disease (ASD). These short comings have led to the development of new motion preserving devices in the form of cervical arthroplasty (CA). Over the last 20 years we have seen a rapid growth and improvement in these devices and the associated surgical techniques. This brief overview

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describes a practical approach for the rationale and patient selection for CA. The current and upcoming devices and their kinematic characteristics are discussed along with relative strengths and weaknesses. Material selections as well as fixation methods are described along with current results of large randomized trials. Finally, the complication profile and techniques for complication avoidance are reviewed.

Why Consider Cervical Arthroplasty?

The goal of CA is to reduce or eliminate ASD by preserving spinal kinematics at the operative and adjacent levels. Arthroplasty is motion-sparing, but may also restore normal spinal motion following traditional fusion techniques. Symptoms of neck pain, radiculopathy or myelopathy, referable to an adjacent level degeneration following fusion, has been reported to occur at rate as high as 2.9% per year following the initial operation, with a cumulative rate of 25% by 10 years [3]. Biomechanical studies have supported clinical observations by demonstrating increased mechanical stress on adjacent discs following cervical fusion [4] and the avoidance of early ASD changes with CA [5]. Nevertheless, the concept of ASD remains unproven and the incidence of ASD versus natural history of cervical spondylosis remains controversial.

Robertson [6] reported 2-year follow-up on 232 patients undergoing either ACDF or CA, and found a significantly higher rate of radiographic and clinical ASD in the ACDF group. Rabin [7] first described increased translation at adjacent levels post-ACDF when compared with CA.

Sasso [8] also demonstrated similar results with increased translation occurring at the superior adjacent level following ACDF when compared with CA. Recently, McDonald [9] demonstrated that patients treated with ACDF have greater adjacent segment vertebral rotation and facet translation, as well as in remote segments two levels cranial to the index level. This study is strengthened by the assessment of dynamic vertebral motion in vivo and in three dimensions. In comparison, Lee [10] utilized three-dimensional motion analysis to demonstrate significantly retained flexion and extension in CA patients at 1 and 6 months post-operatively. Preservation of range of motion and cervical kinematics have also been demonstrated in CA patients at 1 [11,12], 5 years post-operatively [13]. Long term follow-up of larger patient populations will be required to confirm the radiographic, clinical and kinematic differences between ACDF and CA, and to determine whether the hoped benefit of preventing adjacent segment disease is realized.

Cervical Arthroplasty Devices

Clinical Trials

Current Food and Drug Administration (FDA) Investigational Drug Exemption (IDE) trials are designed to demonstrate safety and equivalence of CA, not efficacy (superiority of the investigational device compared to standard intervention). These studies are prospective multicenter trials, in which patients were randomized to undergo arthroplasty or fusion surgery, and success is defined as a composite score based on validated clinical scales. Previous reviews have thoroughly documented these trials and related studies [14-16].

CA devices that have been evaluated and are currently FDA-approved for clinical use include the Prestige (Medtronic Sofamor Danek, Memphis, TN, USA) [17], Bryan (Medtronic Sofamor Danek, Memphis, TN, USA) [18], ProDisc-C (DePuy Synthes, West Chester, PA, USA) [19], SECURE-C (Globus Medical, Audubon, PA, USA) [20], PCM (NuVasive, San Diego, CA, USA) [21] and Mobi-C Cervical Discs (LDR, Austin, TX, USA) [22,23]. A summary of the pertinent results of

Table 1. Summary of FDA approved CA devices at 2 years follow-up.

Device	Company	Grup	# of Patients	Overall Success (%)	Average ROM (°)	Subsequent Surgery (%)
Prestige	Medtronik	CA	276	79,3	7,6	1,8
		ACDF	265	67,8		8,7
Bryan	Medtronik	CA	242	85,1	6,5	3,7
		ACDF	221	72,5		5,4
ProDisc-C	DePy Synthes	CA	103	7,3	8,4	1,9
		ACDF	106	68,3		8,5
SECURE-C	Globus Medical	CA	240	83,8	9,7	2,5
		ACDF	140	73,2		9,7
PCM	NuVasive	CA	189	75,1	5,7	5,2
		ACDF	153	64,9		5,4
Mobil-C (1 level)	LDR	CA	164	73,6	10,8	1,2
		ACDF	81	65,3		6,2
Mobil-C (2 level)	LDR	CA	225	69,7	10,1*/8,3 †	3,1
		ACDF	105	37,4		11,4

*CA: Cervical arthroplasty, ACDF: Anterior cervical discectomy and fusion, ROM: Range of motion, *: Superior level, †: Inferior level*

FDA-approved devices is listed in Table 1.

A number of additional devices are in various stages of the class 3 regulatory pathway including the Kineflex|C Cervical Disc (SpinalMotion, Mountain View CA, USA) the Freedom Cervical Disc (AxioMed, Garfield Heights, OH, USA), Synergy Disc (Synergy Disc Replacement, Inc., Toronto, ON, Canada) and M6-C Cervical Disc (Spinal Kinetics, Sunnyvale, CA, USA) [24,25].

The Discover Cervical Disc (DePuy Synthes) was also evaluated compared to ACDF [26,27]; however an FDA submission for approval of this device in the US has been abodonned. Interestingly, a study employing a superiority design (as opposed to non-inferiority) did not demonstrate superior clinical outcomes of this device compared to ACDF [28].

In summary, there is level I evidence that arthr plasty provides equivalent outcomes to fusion with respect to post-operative pain and neurological function. When the results of these randomized controlled trials are pooled and analyzed, there is evidence to suggest that arthroplasty is associated with superior outcomes measures and lower rates of secondary surgery and ASD at 2 years follow-up [29-31].

Long-Term Outcomes of Cervical Arthroplasty

Although initial trails are promising, the efficacy of CA has yet to be proven over longer time periods beyond 2 years. Burkus [32,33] reported the results of both 5 and 7 years of clinical follow-up using the Prestige Cervical Disc, and found that CA maintained a greater range of motion and had lower revision rates compared to ACDF. Adjacent level surgery tended to be lower in the CA group, although this did not reach significance at 5 years. However, this reached significance when analyzed at 7 years, suggesting a potential for reduction of adjacent level degeneration over time with CA. Similarly, Philips [34] reported that arthroplasty with the PCM Cervical Disc demonstrated superior clinical outcomes, with lower ASD and a trend towards fewer secondary surgeries compared to ACDF at 5 and 7 years. Zigler [35] analyzed the clinical outcomes of the

ProDisc-C at 5 years, and found CA patients to have significantly less neck pain, as well as lower re-operation rates as compared to ACDF. In a study evaluating 3 different devices, Nunley [36] found that the development of ASD does not significantly vary between

CA and ACDF at 4 years. Interestingly, concurrent lumbar degenerative disc disease at the time of cervical surgery appears to predict the incidence of cervical ASD development. In a 6 year follow-up evaluating the Bryan and Kineflex|C Cervical Discs, Coric [37] found that both CA and ACDF demonstrated similar index and adjacent level reoperation rates.

Patient Selection

As experience in CA increases, the clinical and imaging criteria for ideal patient and device selection will continue to evolve.

Indications/Contra-Indications

The goals of ACDF are to decompress the neural structures, provide segmental stabilization, and restore segmental lordosis and disc height. The goals of arthroplasty are fundamentally the same, with the exception of motion preservation: (1) decompress neural structures, (2) restore or maintain intervertebral motion and (3) restore segmental lordosis and disc height. Because the decision to proceed with anterior decompression is based on radiculopathy or myelopathy and independent of the method of reconstruction, any patient that is a candidate for single or multilevel ACDF for degenerative disease is also a potential candidate for cervical arthroplasty [38]. Fay [39] reported on the use of CA in 72 patients with myelopathy and 53 patients with radiculopathy, and found clinical and radiographic outcomes to be similar; thus, CA is a viable alternative to ACDF for both presentations of cervical degenerative disease. Auerbach [40] found that 43% of all patients undergoing cervical spine surgery met the strict inclusion/exclusion for CA. The international experience encompasses a much broader set of clinical indications.

Important contra-indications unique to CA include loss of cervical lordosis as well as radiographic instability on lateral or flexion/extension radiographs defined as translation greater than 2 mm and/or ≥ 11 degrees of angulation. Prior to selecting CA, available imaging should be evaluated for evidence of auto-fusion with bridging osteophytes, facet arthrosis or severe loss of disc height at the index level. The presence of these advanced degenerative changes will increase the risk of early or delayed heterotopic ossification (HO) and ultimate fusion post-CA.

Imaging

Pre-operative assessment with static and dynamic cervical spine radiographs is fundamental to proper patient selection. Upright, standing lateral neutral films are used to assess global lordosis of the cervical spine as well as segmental angle and disc height at the index level. Several studies have suggested that a straight or kyphotic deformity of the cervical spine is a contraindication for CA [41,42]. A normal lordosis must be present both globally (C2-7) and at the surgical level. In addition, severe loss of disc height at the index level is a relative contraindication for CA. The minimum disc height in the current generation devices is 5mm. Insertion of devices with a greater height may lead to "over-stuffing" the disc space and limited range of motion of the device and hence a 5mm disc height for the implant will be optimal in most cases. Prior to surgery, dynamic studies are necessary to establish the presence of motion at the index level. For best post-operative results, a minimum of 4 degrees should be present at the index level between preoperative flexion and extension images.

In all cases, a magnetic resonance imaging (MRI) study is required to evaluate anatomic details relating to the spinal cord, nerve roots and disc herniation and/or osteophyte formation.

Computed tomography (CT) is valuable in evaluating facet overgrowth or advanced bony changes which may be a contra-indication for arthroplasty.

Multi-Level Disease

Patients who present with radiculopathy and/or myelopathy often have multi-level cervical disc disease [2]. Although multi-level ACDF is a common operative approach, biomechanical studies have demonstrated that these procedures result in increased intervertebral disc and bone stress of adjacent segments during normal range of motion [43,44]. Thus, CA is a topic of interest in multi-level pathology due to the purported preservation of range of motion. Goffin [45] initially reported on the feasibility and success of performing two-level CA. Subsequent studies have demonstrated equivalent or superior clinical outcomes when comparing single level to multilevel CA [46-48]. In comparison to ACDF, there is evidence to suggest that CA demonstrates improved clinical outcomes; although there are few studies available that evaluate this issue [16,23,49]. The Mobi-C Cervical Disc is currently the only FDA-approved device for one or twolevel disc replacement, and has been demonstrated to maintain effectiveness at 2 and 4 years following implantation [23,50]. In vitro studies have also demonstrated significantly lower pressure on adjacent discs with two-level CA compared to ACDF [51]. Currently, there are not enough clinical studies at this time to perform a thorough analysis of multi-level CA versus ACDF, although there is evidence to suggest that multi-level CA is as safe and effective as single-level surgery [52].

Cervical Arthroplasty Design and Implantation

There are a number of CA devices that have been released or are under development; each having unique features, benefits and disadvantages. Understanding of the kinematics, device design, clinical results and complication profile will allow the surgeon to individualize the device selection.

Device Design and Kinematics

Most implants have either a single or double articulation surfaces with the first generation of implants having a geometry of articulations including ball-and-socket, ball-and-trough, bi-articulating and saddle designs. Apart from the saddle designs, almost all other devices employ a spherical interface with or without translation. Independent translation (distinct from rotatory translation) allows for a mobile center of rotation (COR). Artificial cervical disc replacements that allow for a mobile COR have a theoretical advantage in providing normal kinematics over a range of device positions [53]. Cervical disc replacements with a ball and socket design (e.g., ProDisc-C) provide a fixed COR and thus require precise device placement to restore normal kinematics. With such devices, posterior placement is essential.

The second generation of CA devices has incorporated varying degrees of axial compression into the device design. The M6 Cervical Disc describes compression in the polyurethane core, much like the Bryan Cervical Disc. Unfortunately, despite a large international experience with the M6, no literature has substantiated the benefit of compression over the first generation of CA devices. Although upcoming devices include elastomeric designs, there is a paucity of literature describing the wear debris and material longevity. In addition, the long-term stability of

both the M6 and elastomeric implants has been questioned based on the constrained designed, with the core attached to the endplates. This design results in all motion stress being transferred to the bone-implant interface and the subsequent risk of implant migration and loss of fixation.

Devices can be classified as unconstrained, semi-constrained and constrained depending on the degree of freedom allowed by the device design. Unconstrained devices are dependent on the surrounding soft tissue at extremes of motion, relying on the integrity of the facets and posterior tension band to limit shear and torsional stresses. This is of particular relevance in device selection in the setting of previous cervical spine surgery where unconstrained devices may not provide the necessary stability and safety. Sekhon [54] described a collective experience of 15 patients who had previously undergone cervical spine surgery who subsequently underwent CA (insertion of 24 devices). No device failures were reported in the setting of previous posterior decompression. In a single patient, hyper-mobility developed with internal subluxation and failure of the device when CA was performed adjacent to a two-level fusion [54]. To assess the immediate stability and the role of soft tissues after cervical arthroplasty, Duggal used a cadaveric model comparing CA and the intact spine: the prosthesis provided 63, 45 and 69% of the strength of a normal spine during flexions, extension and axial rotation, respectively [55]. In most settings, a semi-constrained device design provides the best compromise of safety and kinematics.

Materials

Like other artificial joint implants, excessive wear debris is associated with osteolysis, implant loosening and failure, and local and systemic tissue reactions. It is uncertain whether the artificial large joints are truly analogous to cervical disc replacement given that the cervical disc space is relatively avascular, non-synovial and subjected to only the weight of the head (70 newtons). Most designs have either a metal-on-polymer or metal-on-metal articulation. Apart from Prestige LP, most metal on metal designs have been abandoned. For example, the Kineflex|C Cervical Disc completed a FDA IDE trial, which was reported by Coric [24], and then aborted the release of the metal on metal design, favoring a redesign.

Despite extensive preclinical testing, elastomeric implants have an unknown wear debris profile. Safety testing for cervical disc replacements necessitates wear debris testing for implants that have undergone 10 million cycles of fully coupled motion. Unfortunately, no information is available regarding how implants with elastomeric materials compare with traditional, time tested materials such as polyethylene or polyurethane.

Any material consideration must incorporate imaging characteristics, particularly whether the spinal cord and nerves can be visualized post CA with MRI. Imaging compatibility is of particular relevance in the setting of cervical myelopathy or non-symptomatic adjacent segment disc degeneration. In both of these instances MRI of the index or adjacent levels may be required post CA. Sekhon [56] first described imaging characteristics comparing four available disc replacements and found cobalt-chrome-molybdenum alloys prevented accurate postoperative assessment at the surgical and adjacent levels. Titanium endplates, with or without polyethylene are now universally incorporated into the design of the current generation of devices [56].

Fixation Methods

Long-term stability is provided by bony ingrowth between the device endplate and bone interface. The immediate stability of the im-

plant, pore size, pore geometry and surface coatings influence the extent and rapidity of bony in-growth [38]. A number of surface coatings including calcium phosphate, hydroxyapatite and plasma-sprayed titanium have been utilized to improve bone in-growth and long-term stability. Keels, teeth, spikes, rails and screws have all been utilized for achieving immediate stability. Keels and rails have the advantage of immediate press-fit stability. Unfortunately, large keels and rails typically require cuts into both the cortical and cancellous components of the bone, with the risk of releasing osteo-inductive factors that may promote HO and fusion across the disc space [57]. Perhaps more invasive, the Bryan disc requires concave milling of the bony endplates for a precise fit with the biconvex endplates of the device. Spikes and teeth have the theoretical advantage of minimal endplate preparation and less injury to the cancellous bone. However, teeth or spikes require some degree of "settling" into the endplates (which may take days to weeks), and may predispose to "toggle" or movement at the bone-device interfaces in the early post-operative period. The mode of fixation is also a definite consideration when considering multilevel CA. Datta [58] reported a sagittal split fracture in a multilevel cervical disc replacement with the ProDisc-C. Similarly, Pickett [59] described over-milling of intervening bone during the insertion of a two-level Bryan disc, resulting in only 2-3 mm of bone separating the artificial discs. Stress on the intervening bone in multi-level cases should be considered.

The use of non-steroidal anti-inflammatory drugs (NSAID) are known to inhibit ossification when given in the early post-operative period following cervical arthroplasty [60]. In our center, patients are treated with NSAIDs for 2-4 weeks, depending on the extent of endplate preparation required for device insertion. Universally, the use of NSAIDs should be advocated to minimize the risk of HO.

Complication Profile

Surgeons planning to undertake CA should be aware of patient selection criteria and common pitfalls to avoid potential complications.

Sagittal Balance

One of the single most commonly reported complication relating to CA is post-operative kyphosis. Pickett [59,61] initially reported a loss of lordosis (mean of 6 degrees) at the surgical level in a limited cohort and then published a larger series, and found that 49% of inserted artificial discs (n=96) demonstrated varying degrees of kyphosis on lateral neutral radiographs.

Subsequently a number of papers have studied the incidence of post-operative kyphosis, with rates ranging from 20-77% [41,42]. An emerging contra-indication for CA is the presence of pre-operative straightening or kyphosis of the cervical spine [62]. In our experience, with the first generation and compression devices, patients with a pre-operative straightening or kyphosis of the cervical spine have an unpredictable, unacceptably high risk of worsening of kyphosis following CA (Figure 1). Analogous to fusion, patients with post-operative CA kyphosis may have increased incidence of neck pain and poor clinical outcomes [59]. Recently, Kim [63] and McAfee [29] found only 36% of patients with a pre-operative lordotic alignment were able to maintain lordosis following insertion of a ball and socket CA device. A number of avoidance strategies have been proposed, however these should be interpreted with caution [64]. Rabin [65] examined the effect of device endplate orientation and range of motion and found that devices inserted with a lordotic endplates orientation were associated with restricted range of motion from neutral to extension. Given that the existing devices are not

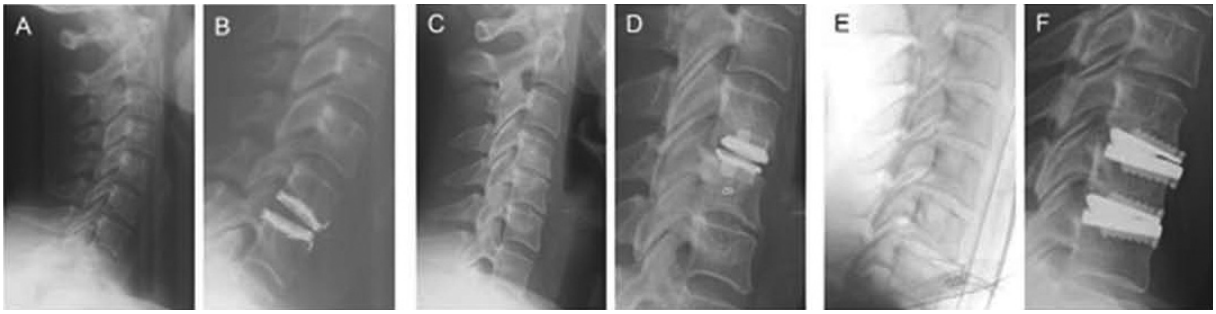

Figure 1. Pre- and Post-oprative device kyphosis with three different device designs: a, b) biarticulating Bryan disc; c, d) ball-and-socket ProDisc-C and e, f) ball-and-through Prestige LP.

designed to actively correct sagittal alignment, device endplates should be inserted in a parallel orientation to ensure predictable impact on alignment and to maximize the implant range of motion.

Two fundamental strategies have been proposed to overcome the challenge of incorporating lordosis into a disc replacement. Du [66] recently described early clinical results with the Discover Cervical Disc. The Discover disc incorporates 7° of lordosis evenly distributed in the device endplates, requiring precise endplate preparation and sculpting to receive the prosthesis [66]. Despite the lordotic endplates, however, the Discover disc has been reported to assume a kyphotic orientation [66]. The Synergy Disc (Synergy Disc Replacement, Inc., Toronto, Canada) incorporates a lordotic geometry into the device core and claims controlled deformity correction in the sagittal plane while restoring physiologic range of motion (ROM) (Figure 2). The kinematic outcome of a small subset of single level Synergy Disc patients has been previously compared with Bryan and ProDisc-C patients and demonstrated superiority in alignment correction over traditional ball and socket devices [67]. It remains to be seen whether incorporation of lordosis into the endplates or polyethylene core are equally effective in preserving and/or correcting pre-operative sagittal balance.

Subsidence

Little has been published regarding rates of subsidence in CA. Goffin [45] outlined a case of implant subsidence and suggested the following techniques to minimize its occurrence: preserve structural integrity of the vertebral endplate; use

Figure 2. Synergy disc schowing device endplates maintained at a 6° lordotic configuration in the neutral position.

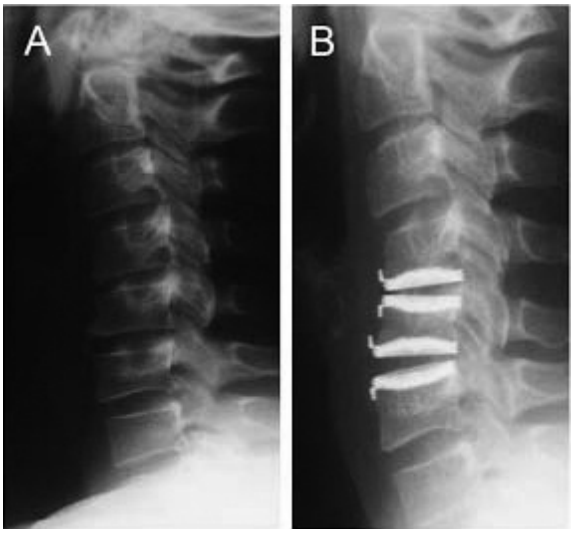

Figure 3. Post-operative change in alignment and motion in multilevel CA: a) pre-operative lateral radiography, b) post insertion of caudal implant, resulting loss of alignment and motion of rostral disc replacement.

the widest possible device footprint to engage the strong peripheral bone; do not use implants with a large height in the setting of a collapsed disc and avoid CA in the setting of osteopenia, metabolic bone disease or medications that may alter bone quality.

Implant Migration

Migration has been a seldom reported complication for CA. Goffin [45] described a single case in large series of patients receiving either single or multilevel CA. Pickett [59] described 2 cases of endplate migration in 96 disc insertions. In our experience we have encountered early migration of device endplates in multilevel CA cases. In instances where the implants are not precisely aligned in both the coronal and sagittal planes, endplate migration of the first implant following insertion of the second device can occur. In many cases the superior implant acts a "slave" to inferior prosthesis, with the inferior prosthesis having improved stability, alignment and range of motion (Figure 3a, b).

In a separate observational case-series of 808 interventions (925 prosthesis) through SWISS spine, four (4) intraoperative complications (3 dura lesions and 1 blood vessel injury) and 23 revisions were documented related to 691 single-level surgeries [46]. Two (2) complications (1 blood vessel injury and 1 vertebral body injury) and six (6) revisions were documented for 117 multi-level surgeries.

Early and Delayed Fusion

HO following CA refers to the process of bone formation bridging across the disc space level containing the disc replacement. First identified as a complication following total hip and knee arthroplasty, HO can occur both in the early and late post-operative periods following CA [59,68]. McAfee [69] devised a grading classification of HO in lumbar disc arthroplasty, based onthe analysis of approximately 10,000 radiographs in 365 patients. The reported incidence of HO in CA is variable throughout the literature, and the predisposing factors and long-term effects are currently unclear. Mehran [57] reported a high rate of HO in 77 ProDisc-C insertions. Only 33% of patients did not have evidence of ossification, and at one year 9.1% of patients demonstrated a spontaneous fusion at the surgical level. In 90 patients, Leung [70] found that 17.8% developed HO following implantation of the Bryan disc. Development of HO following Mobi-C insertion has been reported between 64.3 and 67.1% [71,72].

The development of HO has been proposed to involve three conditions: osteogenic precurso cells, inducing agents and a permissive environment [73]. Male gender and advanced age have been identified as two possible risk factors for the development of HO [70]. Yi [74] performed a retrospective study to further elucidate the predisposing factors of HO. In particular, the authors were interested in the potential influence of pre-existing degenerative changes on the development of HO. This study evaluated 170 patients who underwent CA with the Bryan, Mo-

bi-C or ProDisc-C implants, with an overall HO development of 40.6%. Interestingly, only male gender and implant type were found to be statistically significant predictors of HO development, and not pre-existing degenerative changes. Gender-specific effects were purported to be hormone-related, whereas implant differences were attributed to design and insertion techniques. In addition, the development of HO was not significantly different between single and multi-level CA [52].

Despite the relatively high incidence of HO following CA, the clinical significance of this development is unclear. Leung found a positive relationship between the development of HO and the loss of segmental movement [70]. However, Barbagallo [75] have since reported that, despite the development of HO following CA, clinical and functional improvement is maintained for 3 years following surgery. Additional retrospective studies evaluating the Mobi-C disc in 28 patients, and Discover disc in 171 patients similarly found that the development of HO does not predict a negative clinical outcome [72,76].

A meta-analysis by Chen [77] evaluated the prevalence of HO following implantation of multiple devices, including the Bryan, ProDisc-C, Mobi-C, Prestige and M6-C discs. They identified a pooled prevalence of 44.6% at 1 year, and 58.2% at 2 years follow-up postoperatively.

Prevalence of advanced HO (Grade 3 or 4) was 11.1% and 16.7% respectively. Despite this high prevalence, clinical improvement is unrelated. However, these results should be interpreted with caution, and long-term data are needed to identify the correlation of HO development with functional outcomes.

Perioperative prophylaxis for HO has been well-documented in the orthopedic literature, including the use of radiotherapy and NSAIDs [69]. As radiotherapy is not an option due to the potential for spinal cord injury, NSAID use has been favored in certain studies. Heller [78] described the need for NSAIDs following insertion of the Bryan disc. In our experience, HO post-CA can be minimized by the following: 1) avoidance of excessive longus colli dissection; 2) minimize endplate drilling; 3) avoid under-sizing the implant in the anterior-posterior plane; and 4) routine use of NSAIDS for a minimum of 2 weeks (Figure 4).

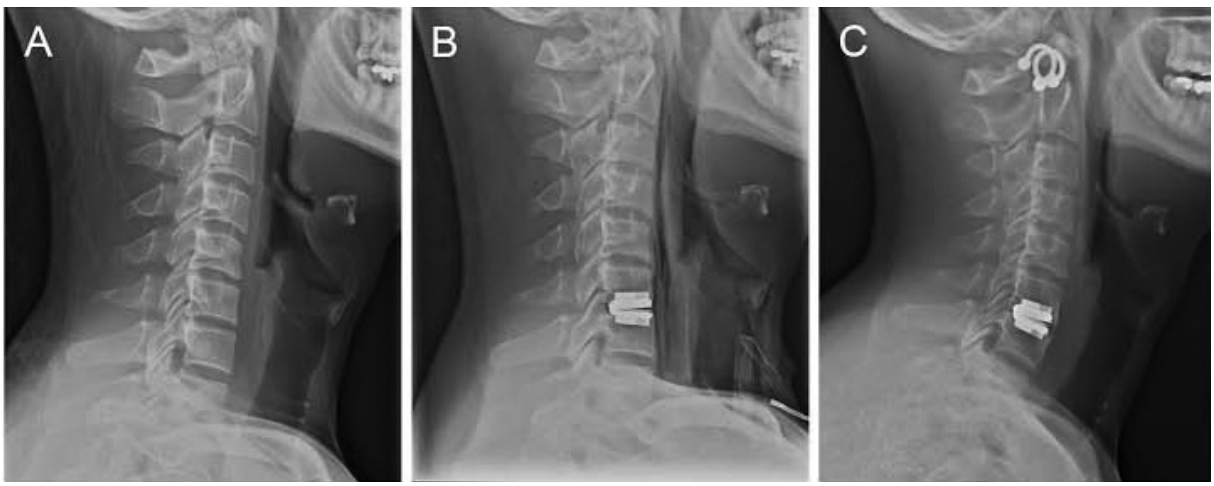

Figure 4. Delayed fusion post ProDisc-C insertion: a) Pre-operative neutral lateral radiograph, b) immediate post-operative neutral lateral radiography and c) late post-operative neutral lateral radiograph demonstrating bridging anterior osteophytes (with loss of motion).

Dysphagia and Dysphonia

Dysphagia and dysphonia are well-known complications of anterior cervical approaches, reported as high as 30% at 3 months post-operatively [79]. The development of dysphagia is likely multi-factorial, and proposed mechanisms include local denervation, excessive retraction duration or pressure, or post-operative changes [80]. In a prospective randomized study using validated measures, McAfee [80] reported a similar initial post-operative incidence of dysphagia.

This incidence was then significantly lower in the CA group compared to ACDF in all subsequent follow-up. The authors have suggested this difference is due to less esophageal retraction and the lack of an anterior profile of the CA devices.

Health Economics

Although data are limited, cost-effectiveness analyses have demonstrated superiority for CA compared to ACDF. Assuming a 20-year duration of a CA prosthesis, Qureshi [81] calculated a higher quality-adjusted life year (QALY) at a lower cost ($3042 versus $8760), as well as a net gain of 2.02 QALYs, when comparing CA to ACDF. McAnany [82] included outcome and complication probabilities from existing literature, and found CA to be the dominant treatment strategy at five years. Radcliff [83] performed a retrospective analysis of "real world" patients with single level cervical disease by evaluating insurance industry data. At 2 years follow-up, they identified a significant reduction in total insurance costs ($34,979 versus $39,820) and cost per person, per month ($3,071 and $3,634 at 1 year; $2,291 and $2,874 at 3 years) in favor of CA over ACDF. Patients undergoing CA also return to work more quickly after surgery, although rates were equivalent after 6 months [84]. Steinmetz [85] performed a subgroup analysis focused on workers' compensation patients from the IDE trials of Prestige and Bryan cervical disc replacements, comparing CA and ACDF. Although the results were not statistically significant, a trend for earlier return to work and improved NDI scores were seen in workers' compensation patients treated with CA.

Conclusion

Artificial cervical disc replacement is emerging as a viable alternative to ACDF in the treatment of radiculopathy and myelopathy caused by cervical disc disease. A number of large trials released over the past year have documented the safety of the procedure. Nevertheless a number of unanswered questions still remain. Does maintaining segmental motion affect the development of adjacent segment disease in the long term? Is there any significant clinical benefit to inserting an artificial disc rather than doing an ACDF? These questions and others are increasingly being answered as we gain greater experience and long-term follow-up.

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