ISASS Policy Statement – Cervical Artificial Disc

Domagoj Coric

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2397 Waterbury Circle, Suite 1,
Aurora, IL 60504, Phone: +1-630-375-1432

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Domagoj Coric, MD

Department of Neurosurgery, Carolinas Medical Center, Charlotte, NC USA

Introduction

Morgan Lorio, MD, FACS, Chair, ISASS Task Force on Coding & Reimbursement

The ISASS Task Force reached out to Domagoj Coric, MD to provide a timely summation on cervical disc arthroplasty given his special interest and recent IASP championship of this innovative technology to insure enhanced spine patient access. The ISASS Task Force is pleased with this step towards published ISASS societal policy and applauds Dr. Coric's effort; if ISASS is to continue to succeed we must continually harness the voluntary talents and energies of our members with gratitude.

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Background

Cervical total disc replacement (cTDR) was first introduced in Europe in the late 1990s.[1, 2, 3, 4] Subsequently, three prospective, randomized Food and Drug Administration (FDA) regulated Investigational Device Exemption (IDE) trials were initiated in the US dating back to 2000.[5, 6, 7] These initial IDE studies ultimately led to the first three FDA approvals for cTDR devices in the US, Prestige ST[5] (Medtronic- 541 patients, 32 sites) (2007), Prodisc-C[6] (Depuy Synthes- 209 patients, 13 sites) (2008) and Bryan Disc[7] (Medtronic- 463 patients, 30 sites) (2009), for the treatment of 1-level cervical spondylosis from C3-7. There have been an additional three FDA approvals, Secure-C[8] (Globus Medical- 380 patients, 18 sites), PCM[9] (Nuvasive- 342 patients, 24 sites) (2012) and Mobi-C[10] (LDR- 1level: 260 patients, 24 sites; 2 level: 339 patients) (2013). There has also been a new indication as Mobi-C was also approved for treatment of two-level cervical spondylosis C3-7.[10]

All the US FDA IDE trials compared cTDR devices to standard anterior discectomy and fusion (ACDF) in prospective and randomized studies producing Level 1 data. As with all industry-sponsored studies, bias, both investigator and patient related, is a concern. This concern was somewhat mitigated by the fact that these IDE studies have cumulatively involved over 2,500 patients at over 100 study sites (Table 1). Furthermore, these studies utilized similar validated outcome measures including Neck Disability Index (NDI), Visual Analog Scale (VAS) and SF-36. ACDF is an established surgical procedure with a

well-documented safety and efficacy dating back 60 years.[11, 12, 13, 14] Cervical arthroplasty offers some theoretical advantages over ACDF.[15, 16, 17]. ACDF results in loss of motion at the index level(s), placing increased stress on adjacent levels above and below the fusion.[18, 19, 20, 21, 22, 23, 24, 25, 26, 27] There is a documented incidence of clinically symptomatic adjacent-level disc disease following ACDF ranging from 0.5-3% annually.[13, 14, 28] Hilibrand et al.[20] reported a rate of symptomatic adjacent-level degeneration following ACDF of 2.9% annually, although the rate of adjacent level re-operation was only 0.7% per year. Similarly, Robertson and associates reported a symptomatic adjacent-segment degenerative disc disease rate of 7% in the anterior fusion series. By preserving motion at the operated level, cTDR has the potential to positively affect the occurrence of adjacent segment degeneration.[29, 30, 31, 32]

Table 1. FDA-approved cTDR devices with number of patients enrolled in pivotal IDE study.

cTDR Device	*# of Patients*
Prestige ST	541
Prodisc-C	209
Bryan Disc	463
Secure-C	380
PCM	342
Mobi-C 1-level	260
Mobi-C 2-level	339
TOTAL	***2534***

In order to establish an evidence based rationale for cTDR as a viable therapeutic modality in the treatment of cervical radiculopathy, cervical artificial discs must satisfy several criteria. They must show clinical efficacy and safety through the regulatory IDE process and receive the appropriate regulatory approval. Additionally, cervical arthroplasty must validate that the technique maintains segmental motion with concomitant decreased adjacent level stresses compared to ACDF. Furthermore, the results of multi-center controlled studies should be replicated at individual centers. Intermediate term data should reaffirm safety and efficacy beyond the two year follow-up mandated by FDA IDE process. Once accepted as reasonable treatment option, long-term data should be utilized to refine ideal indications for that procedure.[33]

Results

The results of seven different prospective, randomized studies have been published in peer-reviewed literature.[5, 6, 7, 8, 10, 34, 35] These studies, comparing cTDR to standard anterior cervical discectomy and fusion (ACDF), have shown positive results for cTDR leading to six different FDA approvals. Although the statistical design of these studies was “non-inferiority.” on numerous clinical end-points, artificial discs were found to be statistically superior to fusion. Mummaneni and colleagues showed statistically significant higher neurological success for the Prestige ST artificial disc.[6] Heller et al and

Coric et al documented statistically significant greater overall composite success rates for Bryan and Kineflex|C, respectively.[5, 34] Davis and associates reported statistically superior overall success for 2-level surgery with Mobi-C.[10] Murrey and associates reported statistically significant decrease in secondary surgeries following Prodisc-C placement.[7] Vaccarro et al showed statistically superiority in favor of SECURE-C in terms of overall success, secondary surgery as well as patient satisfaction.[8] Phillips et al reported statistically significant lower NDI scores and dysphagia rates as well as higher patient satisfaction for PCM.[35]

The composite overall success rate reported from the IDE studies favor arthroplasty over ACDF. The following cTDR devices showed greater composite overall success (Prestige ST 79% vs 68%; Prodisc-C 72% vs 68%; Bryan 83% vs 73%; Kineflex|C 85% vs 71%; SECURE-C 84% vs 73%; PCM 75% vs 65%; Mobi-C 1-level 74% vs 65%, 2-level 70% vs 37%)(Table 2).[10, 17, 34, 35, 36, 37, 38]

Table 2. Composite overall success rates from pivotal IDE study, cTDR versus ACDF.

IDE study	*cTDR*	*ACDF*
Prestige ST	79%	68%
Prodisc-C	72%	68%
Bryan Disc	83%	73%
Secure-C	84%	73%
PCM	75%	65%
Mobi-C 1-level	74%	65%
Mobi-C 2-level	70%	37%
Kineflex/C	85%	71%

Range of motion data from the IDE studies confirm that cervical arthroplasty devices maintain segmental motion (in degrees) at the treated level: Prestige ST (7.7), Bryan (6.5), Prodisc-C (8.4), Kineflex|C (9.8), SECURE-C (9.7), PCM (5.7), Mobi-C 1-level (10.8) and 2-level (10.1, 8.3) (Table 3).[10, 17, 34, 35, 36, 37, 38]

Table 3. Range of motion (ROM) for cTDR devices from pivotal IDE study.

IDE study	*Mean ROM (degrees)*
Prestige ST	7.7
Prodisc-C	8.4
Bryan Disc	6.5
Secure-C	9.7
PCM	5.7
Mobi-C 1-level	10.8
Mobi-C 2-level	10.1, 8.3

Kineflex/C	9.8

The results of these multi-center studies have been replicated with single center results.[1, 33, 39, 40] Coric demonstrated statistically higher overall success rates from a single institution utilizing three different cTDR devices.[33] Jawahar also combined data from three separate cTDR devices and reported clinical equivalence between arthroplasty and fusion, but no change in adjacent level disease at two years.[40] Garrido reported long-term outcomes for the Bryan disc from a single site which favored cTDR on NDI, VAS and fewer additional surgeries.[39] Level 2 and 3 data from single sites outside the United States (OUS) have also shown positive clinical results. Goffin[4] and Kim[41] reported safety and efficacy with 1- and 2-level cervical arthroplasty using the Bryan disc. Bertagnoli[15] and Beuurain[42] also showed good results with Prodisc-C and Mobi-C, respectively, at two year follow-up.

Intermediate and long-term follow-up studies, ranging from 4- to10-years, have also been published.[31, 43, 44, 45, 46] Burkus and associates reported statistically higher rate of disability (NDI) improvement at 3- and 5-years for cTDR with Prestige ST. They also showed a statistically lower rate of index level surgery for cTDR at 5-years.[43] Similarly, Delamarter et al reported a statistically higher rate of VAS satisfaction at all time points out to 4-year follow-up for Prodisc-C cTDR over ACDF. They also reported a statistically lower rate of index level surgery for cTDR at four years.[46] Zigler et al reaffirmed those positive results out to five year follow-up.[45] Quan reported eight-year outcomes on the Bryan disc using Odom criteria and showed good/excellent results in 90% of patients.[31] Coric et al reported that in both cTDR and ACDF groups, the mean NDI and VAS scores improved significantly by 6 weeks and remained significantly improved from 4- to 8-year follow-up.[44]

There is considerably less literature examining the use of cervical arthroplasty for multi-level cervical spondylosis. Several studies have reported positive results for cTDR in patients with 2-level disease.[4, 41, 47] As previously discussed, Davis et al[10] reported Level 1 data from the prospective, randomized IDE study comparing 2-level cTDR with Mobi-C compared to 2-level ACDF. These authors reported dramatically improved overall success with arthroplasty (70% versus 37%) over fusion.

Several meta-analyses examining cTDR performance have also been published.[37, 38, 48, 49] Bartels et al published a meta-analysis of six peer-reviewed articles and three meeting abstracts. These authors reported statistically superior results for cTDR in pain (VAS) and function (SF-36) at 12 months and disability (NDI) at 24 months, yet concluded that there was no proven clinical benefit for arthroplasty.[48] McAfee and associates combined the results of four separate IDE studies and reported statistical superiority for overall success, neurologic success and survivorship success for cTDR.[37] Upadhyaya and co-authors combined the completed data sets from the first 3 FDA-approved cTDR devices and reported statistically significantly lower reoperation rate for adjacent level disease as well as superior neurological success.[38]

It is well understood that fusion sacrifices motion at the index level and places stresses on adjacent levels.[3, 12, 13, 18, 21, 23, 25, 26, 27, 29, 50, 51, 52] The consequences of those stresses are much less understood. Adjacent level disease is likely a multifactorial process involving several disparate factors including natural history of the underlying disease process

(spondylosis), surgical technique, patient selection and type of instrumentation employed. It is also well established that arthroplasty maintains motion decreases adjacent level stress compared to fusion.[16, 19, 29, 30, 53, 54, 55, 56, 57] But the clinical benefits of this decreased stress remain debatable.[34] It is important to differentiate between adjacent level degeneration (deterioration above or below the operative level evident on radiographic imaging) and adjacent level disease (clinically symptoms attributable to a level above or below the operative level). The only Level 1 studies to document statistically significant decrease in adjacent level disease for cervical arthroplasty are the previously discussed meta-analysis papers by McAfee[37] and Upadhyaya.[38] A decreased rate of adjacent deterioration from the IDE studies in favor of arthroplasty devices was reported by Coric[34] (9% vs 25%), Davis[10](11% vs 23%) and Vaccarro.[8] Kim and associates also reported decreased degenerative change in patients treated with the Bryan artificial disc.[40]

There are several unique complications associated with cTDR devices including subsidence/dislocation, wear debris/osteolysis and heterotopic ossification.[58, 59, 60, 61] The published results of IDE studies generally show low rates of reoperation[43, 46] with the majority of these related to persistent neck pain without device failure. The rate of bridging heterotopic bone across these studies was also low, ranging from 0-3%.[5, 6, 7, 8, 10, 34]

Conclusion

Anterior cervical discectomy and fusion has an established record of clinical and radiographic efficacy.[12, 14, 27, 62, 63] The safety and efficacy of cervical arthroplasty has been established with a growing body of Level 1 evidence that is compelling enough to no longer consider cTDR investigational.[33] This evidence is bolstered by experience with multiple devices, at multiple sites, in and out of the investigational setting and with short-, intermediate- and long-term follow-up. cTDR is a viable alternative to ACDF in select patients with symptomatic 1- and 2-level cervical radiculopathy or myelopathy (Table 4).

Table 4. Indications for cervical total disc replacement (cTDR).

Cervical arthroplasty is indicated in patients meeting the following criteria:

- Skeletally mature
- Clinically symptomatic cervical radiculopathy and/or myelopathy due to neural compression C3-C7 at one-level or two contiguous levels
- Failed at least 6 weeks of nonsurgical treatment or shows signs of progressively clinical deterioration

Clinically symptomatic pertains to one of the following:

- Intractable radiculopathy (arm pain and/or a neurological deficit) with or without associated neck pain
- Myelopathy (due to abnormality localized to the level of the disc space)

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Corresponding Author

Dr. Dom Coric, Email: dom@csna.com

Disclosures

Dr. Coric is a consultant to Pioneer Surgical, Medtronic, Globus Medical, Spine Motion, & Spine Wave. He owns private stock in Spine Motion & Spine Wave.