Single-Level Radiculopathy

Artificial Disc: It Works BETTER than ACDF

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Disclosures

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- Speaker’s Bureau: LDR and K2M
History

Smith and Robinson introduced anterior cervical discectomy and arthrodesis in 1958 as a surgical option for the management of cervical disc disorders\(^1\).


ACDF has gained acceptance as standard of care for patients with persistent radicular and/or myelopathic symptoms that have failed to improve with conservative treatments\(^2\).

20-32% of patients undergoing ACDF developed CASP within 10 years

As longer term results became available, the outcome studies increasingly focused on the potential adverse effects of this procedure.
Similar stress profiles were recorded from intact specimens and those with the artificial joint inserted.

The artificial joint resulted in reduced stresses in the annulus compared with spines with a simulated fusion.
Rationale

• This led the scientists and surgeons to focus their attention towards developing alternative procedures to ACDF
• The concept of “motion preservation technology” was thus born and subsequently led to the development of cervical total disc replacement (c-TDR).
• Since then several total disc arthroplasty implants have been used for treating cervical degenerative disc disease and the clinical outcomes have been published in the literature.
FDA Clearance of Cervical Discs in U.S.

- Prestige ST 2007
- ProDisc-C 2007
- Bryan 2009
- PCM 2012
- Secure-C 2012
- Mobi-C 2013
- Prestige LP 2014
Clinical Outcomes
ACDF Outcomes

Problems

1. Most published results of the ACDF procedure are retrospective and/or anecdotal from experience of a single surgeon or institution, (class III studies at best.)

2. The outcome instruments used and success criteria used for the ACDF studies have varied according to the different authors’ judgment and tools available at the time of data acquisition.
c-TDR outcomes

c-TDR is a class III medical device, so the FDA requires a Investigational Device Exemption (IDE) Trial.

• Abundance of level 1 evidence from these IDE, prospective, randomized, controlled trials

• Interest has led to prospective and retrospective post-market studies

• Subset analysis applies more scrutiny to c-TDR than was ever applied to ACDF
c-TDR IDE outcomes

Studies range from currently enrolling in the clinical trial to approved with 7 year follow-up.
c-TDR IDE outcomes

Studies range from currently enrolling in the clinical trial to approved with 7 year follow-up.

Cervical Disc Arthroplasty with Prestige LP Disc Versus Anterior Cervical Discectomy and Fusion: Seven-Year Outcomes

Matthew F. Goree, MD, J. Kenneth Burkus, MD, Mark E. Saffrey, MD, Hui Nian, PhD, Frank E. Harrell, Jr, PhD

The Orthopaedic Center of St. Louis, St. Louis, Missouri, Wilderness Spine Services, The Haighton Clinic, Columbus, Georgia, Department of Neurosurgery, University of Virginia, Charlottesville, Virginia, Vanderbilt University School of Medicine, Department of Biostatistics, Nashville, Tennessee

Randomized Trial

Long-term Outcomes of the US FDA IDE Prospective, Randomized Controlled Clinical Trial Comparing PCM Cervical Disc Arthroplasty With Anterior Cervical Discectomy and Fusion

Frank M. Phillips, MD, Fred H. Geisler, MD, PhD, Kye M. Gilder, PhD, Christopher Reah, PhD, Kelli M. Howell, MS, and Paul C. McAtee, MD, MBA
c-TDR IDE outcomes

Studies range from currently enrolling in the clinical trial to approved with 7 year follow-up.

Prospective, Randomized Comparison of One-level Mobi-C Cervical Total Disc Replacement vs. Anterior Cervical Discectomy and Fusion: Results at 5-year Follow-up

Michael S. Hiscy, MD,¹ Jack E. Ziegler, MD,² Robert Jackson, MD,³ Pierce D. Nunley, MD,⁴ Hyun W. Bae, MD,⁵ Kee D. Kim, MD,⁶ Donna D. Ohnmeiss, Dr. Med.⁷

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c-TDR IDE outcomes

ProDisc-C reported 7-year follow-up\(^5\)
- Follow-up rate: 92%
- Clinical outcomes were similar between groups
- Secondary surgery rate was significantly different; 7% ProDisc-C vs 18% ACDF (\(p=0.0099\))
Prestige ST reported 7-year follow-up\textsuperscript{6}

- Follow-up rate: 73%
- Significantly different clinical outcomes
  - Mean NDI Improvement: 37.6 Prestige ST vs 32.6 ACDF (p=0.002)
  - Maintenance or Improvement in neurological status: 88.2% Prestige ST vs 79.7% ACDF (p=0.011)
  - Secondary surgery rate was significantly different; 4.8% Prestige vs 13.7% ACDF (p<0.001)
Prestige LP reported 7-year follow-up\(^7\)
- Follow-up rate: 75.9% Prestige LP and 70.0% ACDF
- Secondary surgery rate: 9.6% Prestige LP vs 8.3% ACDF (NS)
c-TDR IDE outcomes

PCM reported 5-year follow-up

- Follow-up rate: 74.8% PCM and 70.3% ACDF
- Significantly different clinical outcomes
  - Mean NDI: 20.4 PCM vs 28.5 ACDF (p=0.001)
  - Mean VAS Neck: 35 PCM vs 25 ACDF (p=0.002)
  - Secondary surgery rate: 8.1% PCM vs 12.0% ACDF (NS)
Mobi-C reported 5-year follow-up\(^9\)
- Follow-up rate: 85.5% Mobi-C and 78.9% ACDF
- Clinical outcomes were similar between groups
- Secondary surgery rate was significantly different; 3.0% Mobi-C vs 11.1% ACDF (p<0.02)
c-TDR IDE outcomes

In addition to long-term clinical outcomes favoring c-TDR, the short term results are also improved:

• Return to work – Faster return to work keeps patients off disability\textsuperscript{10,11}
• NDI – Patients experience faster relief in NDI, significance as early as 6 weeks\textsuperscript{10-13}
Using several analytical approaches that consider multiple sources of uncertainty, CTDR was found to be more effective and less costly than ACDF over 7 years. Our results suggest that CTDR may provide a sustained economic advantage over ACDF."
Other c-TDR studies\textsuperscript{15-21}

Application of Cervical Arthroplasty With Bryan Cervical Disc
10-Year Follow-up Results in China
Yanbin Zhao, MD, Yilong Zhang, MD, Yu Sun, MD, Shengfa Pan, MD, Feifei Zhou, MD, and Zhongjun Liu, MD

Clinical Outcomes of Bryan Cervical Disc Arthroplasty
A Prospective, Randomized, Controlled, Single Site Trial
With 48-Month Follow-up
Ben J. Garrido, MD, Tarek A. Taha, MD, PhD, and Rick C. Sasso, MD
Other c-TDR studies\textsuperscript{15-21}

Eight-Year Clinical and Radiological Follow-Up of the Bryan Cervical Disc Arthroplasty

Gerald M. Y. Quan, MBBS, FRACS, PhD, Jean-Marc Vital, MD, PhD, Steve Hansen, MD, and Vincent Pointillart, MD, PhD

Prospective, randomized, multicenter study of cervical arthroplasty: 269 patients from the Kineflex\textsuperscript{C} artificial disc investigational device exemption study with a minimum 2-year follow-up

Clinical article

\textsuperscript{1}Carolina Neurosurgery and Spine Associates, Charlotte; \textsuperscript{2}Triangle Orthopedics Associates, Durham, North Carolina; \textsuperscript{3}Spine Institute of Louisiana, Shreveport, Louisiana; \textsuperscript{4}Texas Back Institute; \textsuperscript{5}Plano Orthopedic Sports Medicine & Spine Center, Plano; \textsuperscript{6}Gordon Spine Associates, Tyler, Texas; and \textsuperscript{7}Olympia Medical Center, Los Angeles, California
Other c-TDR studies\textsuperscript{15-21}

\begin{itemize}
\item \textit{Comparison between single- and multi-level patients: clinical and radiological outcomes 2 years after cervical disc replacement}

J. Huppert · J. Beaurain · J. P. Steib · P. Bernard · T. Dufour · I. Hovorka · J. Stecken · P. Dam-Hieu · J. M. Fuentes · J. M. Vital · T. Vila · L. Aubourg

\item \textit{Artificial total disc replacement versus fusion for the cervical spine: a systematic review}

Ingrid Zechmeister · Roman Winkler · Philipp Mad
\end{itemize}
Other c-TDR studies


“The evidence from randomised controlled clinical studies has shown that after 2 years CTDR is equal to fusion surgery in terms of outcomes and complications.”


“Compared with ACDF, CDA carry a lower incidence of dysphagia complications and reoperation related to adjacent-segment degeneration, and a higher prevalence of neurological and overall success at 2 years postoperatively… Future large-scale RCTs with long-term follow-up are needed to provide clear evidence”
Other c-TDR studies


“Arthroplasty is associated with a lower rate of secondary surgery and a higher rate of neurological success at 2 years. Arthroplasty may be associated with a lower rate of adjacent-level disease at 2 years, but further follow-up and analysis are needed to confirm this finding.” 24

This study was completed in 2012, with only 3 FDA trials available for review.
Other c-TDR studies


“These findings suggest that cervical arthroplasty is superior to ACDF in overall success, neurological success, and survivorship outcomes at 24 months postoperatively.”\textsuperscript{25}
ISASS Policy statement

“Anterior cervical discectomy and fusion has an established record of clinical and radiographic efficacy. 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 investigative. 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.”
Bottom Line

• Over 2500 patients have been enrolled in FDA IDE trials of currently approved c-TDR devices

• Comparable success rates for both procedures at the average follow-up of 2-7 years

• Likelihood of secondary surgery is as much as 300% increased with ACDF vs c-TDR

• C-TDR is the clear choice for patients with single level DDD
References


References (cont.)


Thank You!