

Cervical Kinematics After Fusion and Bryan Disc

Arthroplasty

Rick C. Sasso, MD and Natalie M. Best, BS

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Introduction: Disc arthroplasty has been shown to provide shortterm clinical results that are comparable with those attained with traditional anterior cervical discectomy and fusion. One proposed benefit of arthroplasty is the ability to prevent or delay adjacent level operations by retaining motion at the target level and eliminating abnormal adjacent activity. This paper compares motion parameters for single-level anterior cervical discectomy and fusion and disc replacement patients at the index level and adjacent segments.

Methods: Radiographic data from patients enrolled in a 23 prospective, randomized clinical trial were selected for kinematic assessment of cervical motion. All patients received either a 25 single-level fusion with allograft and anterior cervical plate (Atlantis anterior cervical plate, n = 13) or a single-level 27 artificial cervical disc (Bryan Cervical Disc prosthesis, n = 9) at either C5/C6 or C6/C7. Flexion, extension, and neutral lateral 29 radiographs were obtained preoperatively, immediately postoperatively, and at regular intervals up to 24-month time points. 31 Cervical vertebral bodies were tracked on the digital radiographs using quantitative motion analysis software (QMA, 33 Medical Metrics) to calculate the functional spinal unit motion parameters including range of motion (ROM), translation, and

35 center of rotation. If visible, the functional spinal unit parameters were obtained at the operative level, and also the37 level above and the level below.

Results: As expected, significantly (P < 0.006 at 3, 6, 12, and 24 mo) more flexion/extension motion was retained in the disc replacement group than the plated group at the index level. The disc replacement group retained an average of 6.7 degrees at 24 months. In contrast, the average ROM in the fusion group was

2.0 degrees at the 3-month follow-up and gradually decreased to
0.6 degrees at 24 months. The flexion/extension ROM both above and below the operative level was not statistically different for the disc-replaced and fusion patients, however, mobility increased for both groups over time. The anterior/ posterior translation that occurs with flexion/extension motion

49 remained unchanged for the disc replacement group at the level above the target disc preoperatively and postoperatively. In contrast, the translation increased for the level above the fusion.61At the 6-month follow-up, the increase in translation was
significantly greater for patients that were fused (P < 0.02) than
for patients that received a disc replacement. This change was
not significant at 12 months.63

Discussion: Previous studies have shown the Bryan disc to
maintain mobility at the level of the prosthesis. The long-term
clinical benefit of maintenance of motion is postulated to be the
ability to delay or avoid adjacent level operations. This study
reveals that there is no difference in flexion/extension ROM at
the level above and below either a fusion or Bryan arthroplasty.6771
There is, however, an increase in anterior/posterior translation
at the cephalad adjacent level in patients with arthrodesis while
the Bryan arthroplasty retains normal translation for the same
amount of flexion/extension at the adjacent level.73

Conclusions: The Bryan disc may delay adjacent level degeneration by preserving preoperative kinematics at adjacent levels.

Key Words: cervical spine, kinematics, arthroplasty, artificial disc, Bryan artificial disc replacement, fusion

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A nterior cervical discectomy and fusion (ACDF) is a proven intervention for patients with radiculopathy and myelopathy.¹ Because of limitations specific to this procedure, investigators have developed alternatives to fusion that attempt to address the kinematic and biomechanical issues inherent in fusing a cervical motion segment. 91

Adjacent segment degeneration requiring reoperation has been documented at a rate of 2.9% of patients 93 per annum by Hilibrand et al.² Other reports have helped to shed light on the recurrence of neurologic symptoms 95 and degenerative changes adjacent to fused cervical levels.^{2–5} In patients undergoing cervical fusion, 25% will have new onset of symptoms within 10 years of that fusion.² Segments adjacent to a fusion are subjected to an increased range of motion (ROM) and increased intradiscal pressures^{6–9}. 101

Intervertebral disc replacement is designed to preserve motion, avoid the limitations of fusion, and allow patients to quickly return to routine activities. It avoids the morbidity of bone graft harvest,^{10,11} pseudarthrosis, complications of anterior cervical plating, and the side effects of cervical immobilization. 107

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 From the Indiana Spine Group and Indiana University School of Medicine, Indianapolis, IN.

Reprints: Rick C. Sasso MD, Clinical Orthopaedic Surgery, Indiana University School of Medicine, Indiana Spine Group, 8402 Harcourt Rd., Suite 400, Indianapolis, IN 46260 (e-mail: rsasso@indianaspinegroup.com).

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1 Artificial disc implantation was first accomplished by Fernstrom¹² in 1966. In the late 1980s, Cummins et AQ2 al¹³ developed a metal-on-metal ball and socket cervical AQ3 disc replacement comprised of 316L stainless steel. In May 2002, the Bryan cervical disc was the first cervical 5 prosthesis to be implanted in the United States as part of 7 a Food and Drug Administration (FDA) Investigation

Device Exemption (IDE) study. The Bryan disc (Med-9 tronic Sofamor Danek, Inc, Memphis, TN) is a one-piece, biarticulating, metal-on-polymer, unconstrained device

with a fully variable instantaneous axis of rotation^{14,15} 11 and is the prosthesis used in this study.

13 One of the primary goals of cervical disc replacement is to reproduce normal kinematics after implanta-

tion. This includes the anterior-posterior translation 15 routinely exhibited during flexion and extension. Motion studies have been conducted on human cadavers in the 17

laboratory^{16,17} but are limited by the mandatory artificial 19 design of in vitro evaluation. The optimal method of

assessing cervical kinematics is in a living human in vivo 21 model. A recent study evaluated in vivo motion with the

Bryan disc postoperatively as compared with preoperative movement.¹⁸ The most valid study design, however, 23 examines a prospective, randomized cohort of arthro-

25 plasty versus a control fusion population. The current study provides these data. This study aims to evaluate the

27 ability of the Bryan disc device to maintain motion at the implanted level and also assess the motion at adjacent 29 segments and compare this juxtalevel movement of arthroplasty to conventional arthrodesis.

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MATERIALS AND METHODS

Patient Population

35 The first 22 consecutive patients enrolled in the Bryan cervical disc arthroplasty FDA IDE trial at one site 37 are the subjects of this study. This is a prospective, randomized assessment of arthroplasty versus ACDF for 39 the treatment of one-level cervical radiculopathy or myelopathy resistant to nonoperative treatment. All 22 41

patients were operated by one surgeon from May 2002 to April 2003. They received either a single-level anterior 61 cervical allograft/plate (Atlantis anterior cervical plate, n = 13) or an artificial cervical disc (Bryan Cervical Disc 63 prosthesis, n = 9) at either C5/C6 or C6/C7. Twelve patients had their procedure at level C5/6 and 10 at C6/7. 65 Thirteen patients (59.1%) were male. At the time of surgery, the patient population's ages ranged from 32 to 67 53 years with an average age of 42.4 ± 5.4 years.

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Evaluation of Kinematics

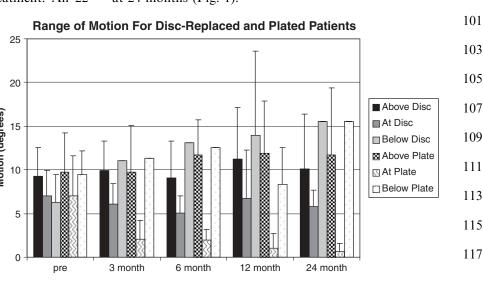
Radiographic data from consecutive patients enrolled in a prospective, randomized clinical trial were selected for kinematic assessment of cervical motion. Flexion, extension, and neutral lateral radiographs were obtained preoperatively, immediately postoperatively and 75 subsequent regular intervals up to 24 months. Cervical vertebral bodies were tracked on the digital radiographs using quantitative motion analysis (QMA) software (Medical Metrics; Houston, TX) to calculate the functional spinal unit motion parameters including ROM, translation, and center of rotation. This feature-tracking 81 software has been used in a number of other studies.¹⁹⁻²¹ If visible, the functional spinal unit parameters were 83 obtained at the operative level, and also the level above and the level below. Translation was measured as 85 displacement of the cephalad vertebral body along a line parallel to the cephalad endplate of the caudal vertebral 87 body and measured as a percent of the length of that endplate.

RESULTS

Significantly (P < 0.006 at 3, 6, 12, and 24 mo) more flexion/extension motion was retained in the disc replacement group compared with the plated group at the index level. The disc replacement group retained an average ROM of 6.7 degrees at 24 months. In contrast, the average ROM in the fusion group was 2.0 degrees at the 3-month follow-up and gradually decreased to 0.6 degrees at 24 months (Fig. 1).

25 20 Motion (degrees) 15 10 FIGURE 1. Flexion/extension ROM for disc replaced and fusion patients; at the target level and also at the adjacent

59 levels.



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1 The flexion/extension ROM both above and below the operative level was not statistically different for the 3 disc-replaced and fusion patients, however, mobility increased for both groups over time (Fig. 1). The mean 5 anterior/posterior translation that occurs with flexion/ extension activities remained unchanged for the disc 7 replacement group (8.3% of endplate preoperatively, 8.4% at 6 mo, and 8.2% at 12 mo) for the level above 9 the disc (Fig. 2). In contrast, the translation increased for the level above the fusion (8.5% of endplate preopera-11 tively, 12.4% at 6 mo, and 11.0% at 12 mo). This increase was dramatic for some fusion patients, but was not 13 uniformly noted (Fig. 3). At the 6-month follow-up, the increase in translation was significantly greater for 15 patients that were fused (P < 0.02) than for patients that received a disc replacement. This change was not 17 significant at 12 months, perhaps owing to variability in level of patient effort.

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DISCUSSION

The long-term clinical benefit of maintaining motion is postulated to be the delay or avoidance of adjacent level degeneration. Disc replacement aims to preserve the normal kinematics in the spine. The Bryan disc is one of several arthroplasty systems currently being investigated for use in the cervical spine. While each of these devices has early outcome data, long-term studies assessing adjacent segment degeneration are still pending.

Wigfield et al²² reported favorable results on a 2year pilot study of the Prestige I Disc designed to address the safety of the technique and to assess the stability of, and motion allowed by, the device. They tried to target patients most at risk for adjacent segment disease. Fifteen
patients were enrolled in the study. Motion was successfully preserved as radiographically demonstrated within an appropriate physiologic range. Device stability was concluded as no devices dislocated.

In a separate prospective nonrandomized study,
 Wigfield et al⁹ compared the effects of the Prestige Disc
 and one-level anterior fusion on adjacent segment

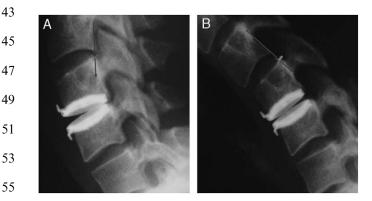


FIGURE 2. A and B, Extension (A) and flexion (B) x-rays of the disc space above a Bryan disc. The translation of the cephalad vertebrae along the cephalad endplate of the caudal vertebrae
 is relatively small.

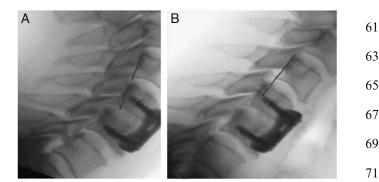


FIGURE 3. A and B, Extension (A) and flexion (B) x-rays of the disc space above a fusion. The translation of the cephalad vertebrae along the cephalad endplate of the caudal vertebrae is relatively large.

motion. No significant difference in adjacent segment79motion was measured between the 2 groups preopera-
tively. Postoperatively, there was a significant increase in
adjacent segment motion in the fusion group (mean 9
degree increase) compared with a slight reduction in
adjacent level motion noted in the disc group. In the
fusion group, adjacent segment motion increased 5% at 6
months and 15% at 1 year. Subgroup analysis showed
that increased motion occurs predominantly in normal
rather than degenerative adjacent discs.81

89 In May 2002, the Bryan Cervical Disc was the first cervical prosthesis to be implanted in the United States. 91 Early clinical studies have shown clinical success and preserved motion at the implanted site.^{15,23–25} Of AO4 <u>9</u>3 particular interest is whether the kinematics are preserved at the operated segment and at adjacent segments. ROM with the Bryan disc has been studied and has shown no 95 significant change in ROM at the operated level and at adjacent levels postoperatively.^{19,20} This study found 97 similar results. However, the strength of this study is that it is a prospective, randomized comparison with the 99 conventional ACDF. One of the major criticisms of ACDF is that it does not preserve the normal kinematics 101 of the spine and therefore may result in degeneration at 103 adjacent segments potentially requiring an additional fusion.²⁻⁹ This study did show preserved motion with the 105 Bryan disc as compared with ACDF. Flexion/extension ROM was not determined to be significantly different between populations at adjacent segments. However, 107 there was a significant difference in translation at the 109 level above the fusion after the surgery. To accomplish similar flexion/extension ROM at the level above the 111 fusion, increased translation was found in the fusion group. This increased translation at the adjacent level 113 may place excessive loads on the annulus and the facet joints above a cervical fusion.

This study showed that the Bryan disc maintains 115 mobility at the level of the prosthesis, comparable with the preoperative ranges. In addition, the study corrobo-117

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- rates the findings of others and demonstrates that an increase in anterior/posterior translation at the adjacent
 level occurs in patients with arthrodesis.²⁻⁹ It is therefore
- postulated that the Bryan disc decreases risk for
 degenerative translational motion. Further evaluation needs to be done once long-term results have been
 obtained.

CONCLUSIONS

Normal flexion/extension ROM continues out to 2 years after Bryan disc arthroplasty. The flexion/extension ROM at adjacent levels to the Bryan disc and a fusion are

- ¹³ not different, but to allow this same motion above a fusion-increased translation is demonstrated.
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