Effect of arthroplasty design on cervical spine kinematics: analysis of the Bryan Disc, ProDisc-C, and Synergy Disc


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Object. Cervical total disc replacement has emerged as a surgical option to preserve motion and potentially avoid adjacent-segment disease after anterior cervical discectomy and fusion. Recently, much attention has been directed at the ability of a given device to maintain and/or restore normal segmental alignment. Nonphysiological disc and segmental angulation could result in increased stresses transmitted to the facet joints and posterior elements, conflicting with the essence of arthroplasty and potentially leading to adjacent-segment disease. The goal of this study was to contrast device alignment and segmental kinematics provided by 3 different cervical disc prostheses.

Methods. Sixty patients were retrospectively analyzed and divided into 3 groups receiving the Bryan, ProDisc-C, or Synergy disc. Only single-level arthroplasty cases were included in the study. Lateral dynamic radiographs of the cervical spine were analyzed using quantitative motion analysis software (Medical Metrics, Inc.) to analyze the kinematics at the index level both preoperatively and postoperatively. Several parameters were noted, including range of motion, disc angles, shell angles, anterior and posterior disc heights, translation, and center of rotation. Preoperative and postoperative data were compared using the Student t-test with a significance level of p < 0.05.

Results. Postoperatively, all 3 disc groups maintained adequate range of motion at the implanted level. With respect to the shell angles, the Synergy disc demonstrated the least variability, maintaining 6° lordotic configuration between the device endplates. In the Bryan disc group, significant shell kyphosis developed postoperatively (p < 0.0001). Both ProDisc-C and Synergy discs significantly increased anterior and posterior disc heights (p < 0.0001). The Bryan and Synergy discs maintained the natural center of rotation, whereas significant anterior shift occurred with ProDisc-C.

Conclusions. The goal for motion preservation at the implanted level was achieved using all 3 devices. The Synergy disc was unique in its ability to alter device angulation by 6°. The Bryan disc demonstrated device endplate kyphosis. Both the Synergy disc and ProDisc-C increased disc space height. (DOI: 10.3171/2010.3.FOCUS1058)

Key Words • cervical arthroplasty • cervical disc prosthesis • kinematics • lordosis • posture control • total disc replacement

Anterior cervical discectomy and fusion is considered the standard of care for treating radiculopathy and/or myelopathy due to DDD. The goals of this combined procedure are to decompress the neural structures, provide segmental stabilization, and restore or maintain lordotic alignment to optimize the chance of neurological recovery.15,23,31,46 Cervical TDR has emerged as an option to preserve motion and avoid potential adjacent-segment disease.4,8,11,13,18,21,28,48 To restore physiological biomechanics and reduce adjacent level forces, the goals of cervical arthroplasty must adhere to the same surgical principles, with the exception of motion preservation—that is, decompress neural structures, maintain intervertebral motion, and restore or maintain segmental lordosis. Although a number of currently available cervical TDRs provide evidence of in vivo ROMs, only isolated devices have specifically incorporated lordosis correction into the device design specifications.29,31,32,35,36,41

Cervical arthroplasty devices come in a variety of designs that provide different kinematic properties once implanted.13 The ProDisc-C disc (Synthes Spine, Inc.) is a cobalt-chrome on polyethylene ball-in-socket single-articulating device that maintains a fixed COR.13 With such devices, posterior placement is essential, whereas devices that allow a mobile COR have the theoretical advantage of providing normal kinematics over a range of device positions. In contrast, the Bryan disc (Medtronic Sofamor Danek) consists of a low-friction polyurethane core
situated between 2 titanium alloy shells and surrounded by a polyurethane sheath. It has double articulation surfaces and independent translation, allowing a mobile instantaneous axis of rotation. Pickett et al.\textsuperscript{29} first demonstrated a mobile COR in an in vivo kinematic analysis of radiographs obtained in patients undergoing cervical TDR with the Bryan disc. The Synergy cervical disc (Synergy Disc Replacement, Inc.) incorporates a novel geometry allowing controlled deformity correction in the sagittal and coronal planes while restoring physiological biomechanics and ROM (Fig. 1). The Synergy disc has a titanium-on-polyethylene articulation with a mobile COR and varying degrees of lordotic correction incorporated into the polyethylene core to provide reliable, predictable correction of cervical alignment.

Despite initial positive clinical results, several reports have documented the occurrence of Bryan disc endplates kyphosis.\textsuperscript{22,32,34,42,43} Several studies have demonstrated a correlation between cervical kyphosis, axial neck pain, new-onset neurological symptoms, segmental instability, and poor functional outcome.\textsuperscript{16,23,25,32} Although authors of recent analyses have reported increased lordosis at the site implanted with the ProDisc-C,\textsuperscript{2,3} Rabin et al.\textsuperscript{35} showed that a lordotic configuration of ProDisc-C endplates was associated with a restricted segmental ROM and translation from neutral to extension. Given that segmental angulation can be influenced by a variety of technical factors—including the amount of endplate drilling, removal of the anterior lip of the superior vertebral body, intraoperative positioning, device angle insertion, and anterior-posterior depth of implantation—\textsuperscript{49} the next generation of cervical TDR designs must incorporate strategies to provide reliable, predictable correction of cervical alignment along with the restoration of physiological biomechanics.\textsuperscript{3,19,49}

In this in vivo retrospective study we analyzed device alignment and segmental kinematics to compare the quality of motion and device angulation provided by 3 differing cervical disc prostheses. A better understanding of the different device designs will ultimately lead to refined indications and device selection with a focus on improving the quality of motion.

**Methods**

The Health Sciences Research Ethics Board at the University of Western Ontario approved this study.

**Patient Population**

Prospective upright (standing) lateral flexion and extension cervical radiographs were obtained in consecutive patients undergoing a single-level ACD followed by cervical TDR. Patients with symptomatic cervical spondylolisthesis demonstrating evidence of retained motion at the affected level on preoperative radiographs were offered cervical arthroplasty as an alternative to arthrodesis. Those with axial neck pain as the predominant or solitary symptom were not offered surgery.

Patients were selected for inclusion in this study based on the following criteria: 1) objective clinical evidence of single-level cervical disc disease causing cervical radiculopathy and/or myelopathy, 2) radiographic evidence of single-level cervical DDD, 3) no response to nonsurgical management for > 12 weeks, 4) a minimum of 6 months of postoperative radiographic follow-up, and 5) a preoperative ROM at the target level > 20°. Patients with traumatic or infectious pathology, clinically or radiographically demonstrated multilevel disc disease, radiographically demonstrated instability, severe facet disease, previous cervical spine surgery, and incomplete data at the last follow-up were excluded. To prevent postoperative pain from impacting the effort of postoperative dynamic cervical radiographs, a minimum of 6 months of follow-up was 1 of the criteria used for patient inclusion in the study. During the period of consecutive patient recruitment, no patient dropped out of treatment and no revision surgery was performed. No patient with a poor clinical outcome or poor disc placement was excluded from the study.

Images from the first 60 consecutive patients undergoing single-level cervical arthroplasty using the ProDisc-C, Bryan, or Synergy discs were selected and retrospectively analyzed in this study; each disc type had been inserted in 20 patients. Standard presurgical assessments included clinical history, neurological examination, and MR imaging. Static and dynamic upright (standing) neutral and flexion and extension cervical radiographs were obtained preoperatively and at 6–12 months postoperatively to assess device kinematics and alignment. Our radiographic technique has been described elsewhere.\textsuperscript{32}

**Surgical Procedure**

A standard right-sided cervical approach for ACD was performed in all patients. Selection of the arthroplasty device was dependent on availability. All devices were implanted as suggested in the product monographs.

**Radiographic Analysis**

Preoperative and the latest postoperative flexion and extension and neutral lateral cervical radiographs were analyzed for each of the disc groups. Independent quantitative motion analysis software (Medical Metrics, Inc.) was used to analyze the kinematics at the index levels. This validated radiographic software uses advanced pattern recognition algorithms to generate accurate measurements of ROM, DA, SA, ADH, PDH, sagittal plane translation, and COR.\textsuperscript{30,40} The SA was defined as the angle between the superior and inferior endplates of the cervical TDR. The COR was obtained for the index and

**Fig. 1.** Illustration of the Synergy disc showing its unique design, which allows the device endplates to maintain a 6° lordotic configuration in the neutral position.
adjacent spinal levels and was reported as X and Y offset from the midline of the superior endplate of the caudal vertebral body.32,33

Statistical Analysis

The means ± SD were determined for ROM, DA, SA, ADH, PDH, translation, COR X, and COR Y. The ANOVA was used to compare results between the 3 disc groups. Further analysis was completed using the Student t-test. A p value < 0.05 was considered significant.

Results

Patient Population

All selected patients met the inclusion criteria. Sixty patients (27 men and 33 women) with a mean age of 45.1 years (range 29–66 years) were included in the study (Table 1). The mean follow-up was 12 months (range 6–24 months). No patients or data were lost at the follow-up. Each patient underwent a single-level disc arthroplasty, receiving 1 of the following disc types: ProDisc-C, Bryan, or Synergy disc. Cervical TDRs were performed from C-3/C-4 to C-6/C-7. There was immediate relief of radiculopathy and/or myelopathy in all cases, with no operative or device-related complications. No delayed complications were observed. All imaging studies had been prospectively collected during the latest follow-up visit and were compared with preoperative radiographs.

Range of Motion

Preoperatively, the patients in the ProDisc-C group had the least ROM. Postoperatively, this group demonstrated a significant increase in the segmental ROM from extension to flexion (preoperative mean 8.0 ± 4.0° vs postoperative mean 10.7 ± 5.5°, p = 0.0003). In cases in which hyperlordosis of the endplates was found in the neutral position, the component ROM demonstrated unequal ROM from neutral to flexion and neutral to extension (Fig. 2). Bryan disc insertion maintained segmental ROM (preoperative 9.5 ± 4.9° to postoperative 8.1 ± 4.3°, p = 0.23). The Synergy group had the largest preoperative ROM (11.1 ± 5.2°). Following surgery, there was no change in the ROM from extension to flexion (8.9 ± 4.4°, p = 0.06). There was no difference in ROM among the 3 devices.

Disc Angle and SA

The mean preoperative DA for the entire cohort of 60 patients was 2.9 ± 4.3°. The DA represents the angle of the diseased disc space prior to surgery. The ProDisc-C preoperative DA at the surgical level was almost parallel at 1.2 ± 3.3°. Following surgery, the mean device SA was 1.1 ± 3.6° (p = 0.64). The postoperative SA was variable, with 3 patients (15%) demonstrating a > 2° worsening of kyphosis at the latest follow-up and 3 patients (15%) exhibiting postoperative hyperlordosis (SA > 5°; Fig. 2).

![Fig. 2. Extension (A), neutral (B), and flexion (C) lateral radiographs demonstrating SA hyperlordosis in the neutral posture following ProDisc-C insertion. Placement of this disc results in unequal motion, with the neutral to flexion ROM of 8° (B–C) but a limited ROM from neutral to extension of 1.2° (A–B).](image-url)
In the Bryan disc group, the preoperative lordotic DA was 3.0 ± 3.1°. Following insertion of the Bryan disc, significant SA kyphosis was found at the late follow-up (−3.4 ± 4.7°, p < 0.0001; Fig. 3). An increase in kyphosis (> 4°) at the index level in the neutral position was found in 60% of patients (Fig. 4).

The Synergy disc demonstrated the least variability with respect to SA. The Synergy disc has a number of lordotic core offerings; the core used in this study had a 6° configuration. The preoperative DA for the Synergy group was 4.6 ± 5.9°. Following insertion of the 6° Synergy disc, the SA maintained a mean of 6.8 ± 2.2° (p = 0.08).

A comparison of the SA between the ProDisc-C and Synergy disc groups revealed a statistically significant increase in lordosis with the Synergy device (p < 0.0001; Fig. 3). Both the ProDisc-C and Synergy discs showed a lordotic SA configuration when compared with the Bryan disc (p = 0.002 and < 0.0001, respectively).

**Disc Height**

Preoperatively, for the entire cohort of 60 patients, the mean ADH was 4.0 ± 1.1 mm, whereas the mean PDH was 3.1 ± 0.9 mm. At the surgical level the ADH increased by 80% (3.4 ± 1.0 mm preoperatively vs 6.1 ± 1.0 mm postoperatively, p < 0.0001) following insertion of the ProDisc-C, whereas the PDH increased by 52% (3.1 ± 0.9 mm preoperatively vs 4.7 ± 0.7 mm postoperatively, p < 0.0001). In contrast, following insertion of the Bryan disc, the ADH decreased by 32% (4.4 ± 1.0 mm preoperatively vs 3.0 ± 1.1 mm postoperatively, p < 0.0001), whereas the PDH decreased by 14% (3.5 ± 0.9 mm preoperatively vs 3.0 ± 1.0 mm postoperatively, p = 0.0005). With the Synergy disc there was a 48% increase in the ADH (4.0 ± 1.0 mm preoperatively vs 6.0 ± 1.3 mm postoperatively, p < 0.0001) and a 32% increase in the PDH (2.8 ± 0.9 mm preoperatively vs 3.8 ± 1.1 mm postoperatively, p = 0.0003).

In comparing the 3 devices, there was no significant difference in ADH between the ProDisc-C and Synergy disc. Both of these disc types presented a significant increase in the ADH and PDH when compared with the heights for the Bryan disc (p < 0.0001). All 3 devices differed from each other with respect to the PDH (p < 0.05 for all).

**Sagittal Plane Translation**

The ProDisc-C disc demonstrated translation of 1.5 mm (0.7 ± 0.5 mm preoperatively vs 1.5 ± 0.6 mm postoperatively, p < 0.0001). Changes in segmental translation induced by the Bryan disc were negligible (p = 0.98). The Bryan disc had 1.0 mm of translation preoperatively and 1.0 mm postoperatively. The Synergy disc had the largest amount of preoperative translation at 1.4 mm, almost double the preoperative translation seen in the ProDisc-C patients preoperatively. After Synergy disc insertion, there was no significant change in translation at 1.2 mm.

There was no different in translation between the Synergy disc and the other 2 devices. Compared with the Bryan disc, there was increased translation in the ProDisc-C (p = 0.03).
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Center of Rotation

At the surgical level, the COR X underwent a statistically significant anterior shift of 0.9 mm after the introduction of the ProDisc-C disc (−0.8 ± 1.2 vs 0.2 ± 0.8 mm, p = 0.002); there were no significant changes in the COR Y values (p = 0.99). The Bryan disc did not significantly change either the COR X or COR Y values (p = 0.16 and 0.27, respectively). Following insertion of the Synergy disc, the COR X underwent an anterior shift (−0.9 ± 0.9 vs −0.1 ± 0.8 mm, p = 0.002). There were significant changes in the COR Y values (3.9 ± 2.2 vs 2.7 ± 2.5 mm, p = 0.006).

When comparing the 3 devices for the COR X and Y, the only difference found was between the Bryan and Synergy disc for the COR X parameter (p = 0.0006).

Discussion

Three cervical disc replacements with different concepts in design and biomechanics were retrospectively compared in this study. Range of motion, the fundamental parameter, was preserved at the implanted site in all devices. The greatest difference between the 3 devices was in the SA measurements. The ProDisc-C disc had a slightly lordotic SA of 1.1 ± 3.6°, with 15% of patients demonstrating worsening kyphosis and 15% showing hyperlordosis (Fig. 2). In contrast, the Bryan disc demonstrated −3.4 ± 4.7° of SA kyphosis, with 60% of patients exhibiting postoperative device endplate kyphosis (Fig. 4). According to the product monographs, to optimize ROM, both the ProDisc-C and the Bryan disc should be inserted into the disc space with the goal of keeping the device endplates in a parallel orientation. The Synergy disc has a unique design, allowing the device endplates to maintain a 6° lordotic configuration in the neutral position while providing a full ROM (Fig. 5). The Synergy disc demonstrated the least variability in SA, with a mean of 6.8 ± 2.2°.

The initial objective of cervical disc replacement was the maintenance of motion at the implanted level, therefore reducing the incidence of adjacent-level disease. Despite favorable short-term clinical results, insertion of the Bryan disc has prompted concerns regarding postoperative kyphosis and cervical alignment. Design limitations and technical nuances can contribute to the poor results in segmental alignment found with the Bryan disc. Factors such as lordotic neck positioning, overdrilling and asymmetry of the vertebral endplates, angle of disc insertion, preexisting kyphosis, and the structural absence of lordosis in the device have been implicated in the development of postoperative kyphosis with the Bryan disc. Studies involving long-term results in patients with cervical fusion have reported the new onset of axial symptoms and accelerated adjacent-segment disease related to focal and segmental kyphosis at the fused level. As stated by Kim et al., the Bryan artificial disc prosthesis has a passive nature in its design, and is not designed to correct kyphosis; hence, one would expect that it would be unable to restore lordosis to [the] spine. In contrast, Rabin et al. showed that a lordotic configuration of ProDisc-C endplates at the surgical level was associated with restricted segmental ROM and translation from neutral to extension. Like the Bryan disc, the ProDisc-C was not designed to actively correct sagittal alignment. An emerging contraindication for cervical TDR is the presence of preoperative straightening or focal kyphosis at the index level. The Synergy disc is differentiated by its 6° preferred lordotic orientation, designed specifically for its unique ability to correct preoperative deformity and/or maintain cervical lordosis (Fig. 6). Our results demonstrated that the Synergy disc maintained a 6.8° lordotic SA alignment.

The preoperative DA for the entire patient cohort (60 patients) demonstrated a relative loss of lordosis due to the degenerative process (2.9 ± 4.3°). Harrison et al. studied 252 asymptomatic volunteers and found that the average lordosis between cervical vertebrae was between 6 and 7°. It is important to note that only healthy volunteers without clinical or radiographic signs of DDD were
considered. Degenerative disc disease is characterized by deterioration and collapse of the intervertebral disc, accompanied by alterations in the spinal curvature. Shim et al. reported a preoperative DA (at index level) of −0.7° (47 patients). Fong et al. studied 10 patients undergoing Bryan cervical disc arthroplasty and found that 40% had angles between 1 and 2° lordosis and 30% were straight (parallel with 0°). Johnson et al. studied 13 patients with a mean preoperative angle of 1° and noted that the symptomatic segment was kyphotic because of a loss of ADH. Changes in disc height can contribute to the loss of the normal cervical lordosis seen in patients with DDD. Traditional fusion strategies have incorporated techniques for the restoration of appropriate lordotic curvature.

Our results lend further evidence to previous studies whose data suggest that a loss of disc space height accompanies DDD. In the ProDisc-C group, the preoperative mean ADH and PDH were 3.4 and 3.1 mm, respectively. For the Bryan and Synergy groups, larger differences were seen between the preoperative ADH and PDH values. Following arthroplasty, both the ProDisc-C and Synergy devices increased the ADH to approximately 6 mm, whereas the Bryan disc decreased the ADH following surgery. Increasing the disc height is important in restoring adequate foraminal height and preventing recurrent nerve root compression. Overdistraction of the disc space, however, can be associated with “overstuffing” and may be associated with both diminished motion of the TDR and facet distraction causing neck pain. The Bryan disc ADH and PDH values were equal at 3.0 mm. Despite the device size, the milling of the endplates required for device insertion may prevent the Bryan disc from restoring adequate disc height. Both the Synergy and ProDisc-C devices in this study had a device height of 5 mm. By virtue of its design, the Synergy disc has unequal values for ADH and PDH, as it has a configuration of a wedge with 6° of lordosis designed into the polyethylene core (Fig. 1).

Range of motion, a fundamental kinematic parameter, was preserved at the index level for all discs: ProDisc-C 10.7 ± 5.4°, Bryan 8.1 ± 4.3°, and Synergy 8.9 ± 4.4°. A comparison between the 3 devices demonstrated no significant difference in the ROM. The ProDisc-C added ROM to the preoperative level, increasing segmental motion by 34%. However, the preoperative ROM for the ProDisc-C group was only 8.0 ± 4.0°, whereas the preoperative ROM for the Bryan and Synergy groups was > 9.0°. Previous studies have already documented significant increases in in vivo and in vitro sagittal motion following insertion of the ProDisc-C. Bertagnoli et al. reported a significant in vivo increase in sagittal ROM (4° preoperatively vs 12° postoperatively) following insertion of the ProDisc-C. DiAngelo et al. described in vitro biomechanical results in cadaveric cervical spines implanted with a single-level ProDisc-C and compared this strategy with single-level ACD and fusion. Following insertion of the ProDisc-C, the surgical level demonstrated a ROM of 13.1°. It is unclear whether there is any clinical benefit to increasing the ROM at the diseased level. In theory, increased ROM may place increased strain on facet joints and uncovertebral joints at the surgical level, potentially causing a negative effect on the index and adjacent-level facets and discs. Alternatively, increased ROM may reduce the potential for autofusion across the arthroplasty level. Longer follow-ups will be required to evaluate the impact of significantly increasing ROM at a functional spinal unit already diseased by the degenerative cascade.

In contrast to the ProDisc-C, both the Bryan and Synergy discs did not change ROM at the index levels. This result may be related to device design with “constraints” incorporated into both devices. With the Bryan disc, a central post and outer membrane sheath limit both translation and ROM. With the Synergy disc, unique soft stops control and prevent excessive sagittal rotation, axial rotation, translation, and lateral bending. For example, in a patient who received a Synergy disc (Case 7; Fig. 6), the preoperative ROM was 19.3°. Following cervical TDR with Synergy, the ROM decreased to 10.6°. In addition to device design, the surgical technique can influence postoperative ROM for the device. Resection of the uncus and division of the posterior longitudinal ligament has been suggested to impact device ROM.

The ProDisc-C incorporates a ball-in-socket joint mechanism with a fixed axis of rotation. Hence, the quality of motion is strictly dependent on the anterior-posterior placement depth and alignment of the device endplates. The COR shifted anteriorly by 1.0 mm (COR X, p = 0.002). As expected, the Bryan disc preserved the physiological location of the COR. The Synergy disc also provided changes in the COR from the preoperative values. Caution must be applied while determining the importance of preserved CORs following cervical arthroplasty. The preoperative parameters observed in our studies cannot be taken as “normal” because all patients had symptomatic single-level disc disease. As such, the lack of significant change in biomechanical parameters in the Bryan disc between pre- and postoperative radiographs implies that the disc was able to maintain the existing preoperative biomechanical properties of the cervical spine. The
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prosthesis, being passive, adapted itself into the local biomechanical profile provided by adjacent vertebral bodies, ligaments, and facet joints. However, Synergy disc implantation resulted in increased disc height and a lordotic SA, changes that would impact COR coordinates when compared with preoperative values. These changes in the COR may represent further deviations from “normal” parameters or, alternatively, a closer approximation of the properties of a healthy native disc.

Study Limitations

Interpreting in vivo x-ray–based kinematic analysis of spinal biomechanics should be approached with caution, especially in a small group of patients. Although kinematics software has demonstrated good reliability and accuracy, the analysis may be limited by patient factors. Out-of-plane motion, pain, and patient effort may introduce variability over sequential films. Patient body habits may obscure anatomical detail in the caudal cervical spine and contribute to error within all kinematic measures. This study addresses only flexion and extension ROM and does not characterize the biomechanical behavior of any of the devices in axial rotation or lateral bending. Analyzing patients after the first 6 months theoretically decreases the influence of postoperative pain and patient discomfort on overall sagittal motion, allowing the cervical prosthesis to settle and the muscles and facet joints to adapt. Also within the first 6 months postoperatively, device endplates are expected to incorporate with the vertebral endplates. Nonetheless, the short-term follow-up in this study, averaging only 12 months, does not address the durability of the devices nor the long-term quality of motion. Long-term evaluation of cervical arthroplasty will require merging of clinical, radiographic, and kinematic information to determine optimal device design.

Conclusions

While limited by a small sample size and a short postsurgical follow-up period, this in vivo study demonstrated that ProDisc-C, Bryan, and Synergy discs adequately maintain ROM at the implanted level. The greatest difference between the 3 devices was in the SA measurements; the Synergy disc provided a 6° lordotic correction following insertion. In addition, there was an increase in the ADH and PDH after implantation of the ProDisc-C and Synergy discs. In contrast, the Bryan disc did not restore disc height and instead produced significant SA kyphosis at the implanted level. Preoperative COR values were fairly preserved among all devices. Longer follow-up is required to assess the durability of kinematic changes at the implanted levels following cervical TDR.

Disclosure

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