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Changes in Sagittal Alignment after Cervical Disc Arthroplasty: Results of a Pilot Study

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Abstract

Background context: For cervical disc replacements to be comparable to the gold standard of cervical discectomy and fusion (ACDF), proper cervical alignment after disc replacement is imperative in preventing accelerated facet degeneration, excessive wear debris and axial neck pain.

Purpose: This study evaluated whether the Synergy Disc (artificial cervical disc replacement) could provide preservation and/or restoration of cervical alignment while normalizing kinematics and providing acceptable clinical outcomes.

Study design/setting: Prospective clinical study for an alignment correcting cervical disc replacement.

Patient sample: The Synergy group was comprised of 37 consecutive patients (42 implants) with a minimum follow-up of 1 year (range 12-26 months) on 34 patients (39 implants).

Outcome measures: Quantitative motion analysis (QMA) software was used for kinematic outcome parameters: range of motion (ROM), horizontal translation, center of rotation (COR-X, Y), disc height (DH), disc and shell angle (DA and SA, respectively). Neck Disability Index (NDI) and Visual Analog Scale (VAS) were also assessed.

Methods: The Synergy Disc patients underwent 204 lateral cervical radiographs (34 patients – 39 implants). Static and dynamic radiological assessments were performed prior to surgery and at last follow-up (mean 18 months, range 12-26 months).

Results: At 18 months post-surgery, the average SA of the Synergy Disc was 6 ± 3° of lordosis. Pre-operative ROM, translation and COR X did not change significantly post-surgery.

Conclusions: The Synergy Disc provided segmental lordosis at the surgical level, while maintaining pre-operative ROM, translation and COR X. There was a superior shift of COR Y following insertion of the device. The lordosis of 6 ± 3° provided by the Synergy Disc was comparable to the lordotic correction provided by an ACDF.

Keywords: Cervical arthroplasty; Sagittal balance; Cervical disc prosthesis; Kyphosis; Total disc replacement; Kinematics; Range of motion

Introduction

Degenerative disc disease (DDD) can result in loss of focal cervical lordosis and disc height [1]. When surgery is required for refractory radiculopathy or myelopathy, the goals of anterior cervical discectomy and fusion (ACDF) have included correction or preservation of cervical alignment following neural decompression [2]. Cervical arthroplasty has emerged as an alternative treatment option in treating cervical DDD, providing the advantage of preserving motion and potentially preventing adjacent segment disease (ASD) [3,4]. For intervertebral disc replacements to be comparable to the gold standard of ACDF, however, disc replacements must be able to provide motion as well as predictable and reliable correction of cervical alignment.

The Synergy Disc (Synergy Disc Replacement, Inc., Toronto, Canada) incorporates a geometry that claims controlled cervical alignment correction in the sagittal plane while restoring physiologic range of motion (ROM). It has a titanium-on-polyethylene articulation with a mobile center of rotation (COR) and varying degrees of lordotic correction incorporated into the polyethylene core (Figure 1). The outcomes of a small subset of single level Synergy Disc patients have been previously compared with Bryan and ProDisc-C patients [5]. Crawford et al. previously reported cadaveric biomechanical and finite element analysis results with testing of alignment control with the Synergy Disc [6]. The goal of the present study was to report the impact on cervical alignment with a larger Synergy cohort, including patients with pre-operative straight or kyphotic segments. Quantitative motion analysis (QMA) software (Medical Metrics, Inc., Houston, TX) was used to evaluate the *in vivo* biomechanical impact on alignment with the disc replacement.

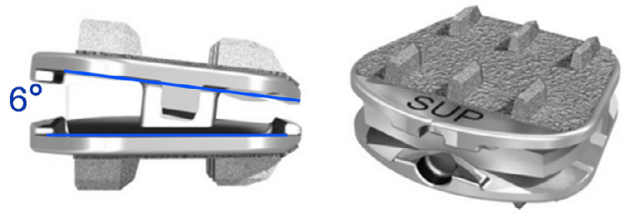

Figure 1: Synergy disc showing device endplates maintained at a 6° lordotic configuration in the neutral position.

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Materials and Methods

Patient population

The Research Ethics Board at the Dokuz Eylul University approved this study. In all cases, surgery was offered to patients who had failed non-surgical management, demonstrated clinical history, physical findings and MR imaging that was consistent with cervical radiculopathy and/or myelopathy.

Thirty-seven consecutive patients with objective clinical and radiographic evidence of DDD causing refractory radiculopathy and/or myelopathy were prospectively enrolled in this pilot safety cohort study for Synergy Disc insertion. Exclusion criteria included radiographic instability, active infection, inability to visualize the affected disc space on optimized lateral fluoroscopy, and less than 2 degrees of motion at the segment in question on dynamic radiographs. Patients with previous cervical spine surgery and length of follow-up less than 12 months were also excluded from this study. A cut off criteria of 12 months follow-up was used as the inclusion criteria based on 5-year retrospective study on cervical arthroplasty by Ryu et al, which found kinematic parameters stabilized by 12 months following surgery [7]. In all cases, patients underwent anterior cervical discectomy (ACD) with excision of the posterior longitudinal ligament, followed by implantation of the Synergy Cervical Disc prosthesis.

A standard, right-sided cervical approach for ACD was performed in all patients. Patients were positioned supine with the neck in neutral alignment. After removal of the disc material and decompression of the spinal cord/nerve roots, minimal endplate preparation was needed for device insertion. No milling or angled endplate preparation was performed. The posterior longitudinal ligament was divided in all cases. Under fluoroscopy monitoring, acute fixation was achieved with self-biting teeth that captured the vertebral body endplates during device insertion.

Using QMA software, the patients were placed in 3 groups based on the alignment of the pre-operative surgical level: nine patients had a parallel disc space (-2° to 2°), while six patients had a focal reducible kyphosis (< -2°) at the index level. The remaining 22 patients demonstrated a pre-operative cervical lordosis (> 2°).

Clinical evaluation

All patients undergoing Synergy Disc insertion underwent routine general and neurological evaluations and were asked to pre-operatively complete the neck disability index (NDI) questionnaire and visual analog scale (VAS) for arm and neck pain in order to measure disease specific and overall well-being outcomes. These questionnaires were re-administered after surgery at 1, 3, 12 and a maximum of 24-months post-operatively.

Radiographic analysis

Independent prospective x-ray analysis of 204 radiographs was carried out by Medical Metrics, Inc., Houston, TX. Static and dynamic standing upright neutral, flexion and extension cervical radiographs were obtained pre-operatively and at all post-operative follow-up visits. Validated radiographic Quantitative Motion Analysis (QMA) software (Medical Metrics, Inc., Houston, TX), was used to analyse the kinematics at the index level(s) [3]. The software uses an advanced pattern-recognition algorithm to generate accurate measurements of ROM, shell angle (SA), disc height (DH), sagittal plane translation and COR in the X and Y direction.

Synergy disc description

The Synergy Cervical Disc is made with a titanium-on-polyethylene articulation, a mobile COR and varying degrees (0° and 6°) of lordotic correction incorporated into 5 and 6 mm height devices (Figure 1). The sagittal and coronal alignment control is incorporated into the polyethylene. Fully coupled ROM is possible. The insertion technique incorporates lordotic trials before insertion of the device. For this pilot study, 6° lordotic cores with a 5 mm height were used in all cases.

Statistical analysis

Mean values and standard deviations (represented after ±) were determined for ROM, SA, DH, translation and COR X and Y. Analysis was completed using a two-tailed Student's t-test with an alpha level set at 0.05. A paired t-test was further used to assess any significant differences between pre and post-operative NDI and VAS scores.

Results

Patient population

Thirty-four patients (29 patients with 1-level and 5 patients with 2-level) were assessed at a mean of 18 months (range 12-26 months) following surgery. Fourteen patients had follow-up equal to or greater than 24 months. The mean age was 44 years (19 males and 15 females). Three patients did not have the required minimum 12-month follow-up evaluation and were excluded. The 3 excluded patients did not demonstrate any complications at the time of 3 and/or 6-month follow-up. All device sizes were used (small 35%; medium 47% and large 18%). All inserted devices had a 6-degree core with a 5 mm height (as measured through the center of rotation).

Surgical levels included: C2-C3 (4%); C4-C5 (12%); C5-C6 (60%) and C6-C7 (24%). There was improvement of radiculopathy and/or myelopathy in all cases, with no complications related to the surgical approach, instrumentation or the device. No explanations or reoperations were performed and no delayed device complications including migration, subsidence, fusion or heterotopic ossification were identified by lateral radiographs during the follow-up period.

Clinical outcomes

There was a 7.9 point improvement in the mean VAS neck pain score at the last follow-up (8.2 ± 1.0 pre-operatively vs. 0.3 ± 0.5 post-operatively, $p<0.05$; Figure 2). Similarly, mean VAS arm pain scores improved by 7.9 points (7.9 ± 0.6 pre-operatively vs. 0 post-operatively, $p<0.05$; Figure 2). Over the follow-up period, mean NDI scores improved by 3.2 points (4.2 ± 0.8 pre-operatively vs. 1 ± 0.2 post-operatively, $p<0.05$). This represented a 56% decrease in NDI scores, suggesting less neck pain post-surgery.

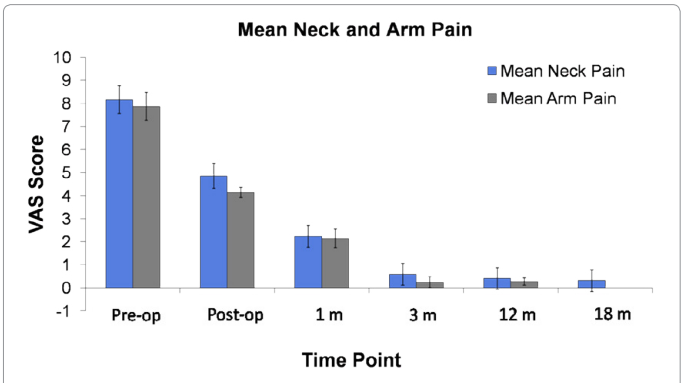

Figure 2: Mean VAS scores for neck and arm pain; bars represent the standard deviations.

Radiographic outcomes

ROM was maintained at the index level following surgery (12 ± 5.2° pre-operatively vs. 9.8 ± 4.2° post-operatively; p>0.05; Figure 3). The Synergy Disc was placed in all mobile segments, including those with a reducible focal kyphosis (Figure 4). The mean pre-operative disc angle (DA) was 4.28 ± 5.45°. In all cases, a 6° lordotic core was inserted into the device. At mean of 18 months follow-up, the average SA of the Synergy Disc was 6 ± 3° of lordosis. There was a significant increase in lordosis at the index level p= 0.007 (Figure 5).

Pre-operatively, the mean DH was 3.5 ± 0.8 mm. Following insertion of the 5 mm Synergy Disc, the DH increased by 37% (3.5 ± 0.8 mm pre-operatively vs. 4.8 ± 1.0 mm post-operatively, p<0.05). Sagittal plane translation did not change following surgery (1.4 ± 1.0 mm pre-operatively vs. 1.7 ± 1.2 mm post-operatively, p>0.05). Similarly, COR X remained unchanged (-0.8 ± 0.9 mm pre-operatively vs. -0.2 ± 0.7 mm post-operatively, p>0.05) while a superior shift occurred in COR Y (3.8 ± 2.3 mm pre-operatively vs. 2.5 ± 2.4 mm post-operatively; p<0.05).

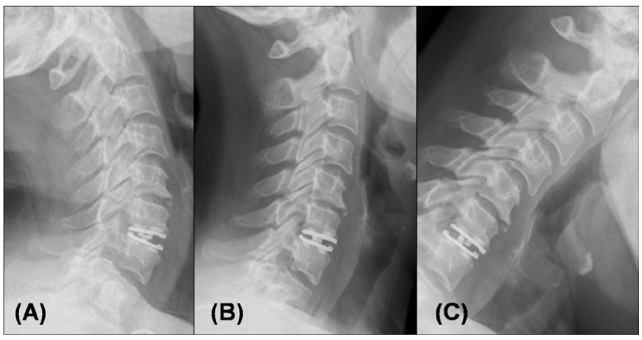

Figure 3: Extension (A), neutral (B) and flexion (C) lateral radiographs 24 months following insertion of Synergy Disc demonstrating 13.9 degrees of ROM from extension to flexion and an upright (B) disc angle of 6.7 degrees of lordosis in neutral.

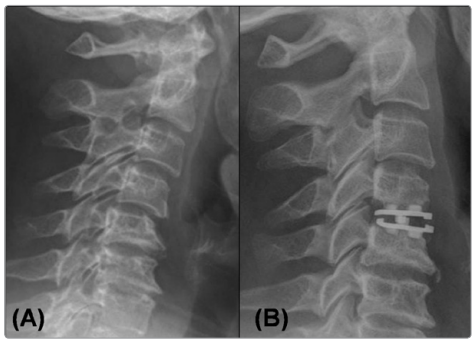

Figure 4: Pre-operative kyphosis at C4-5 (A) and 22 months post-operative standing lateral neutral radiograph (B) demonstrating improved lordosis at the site of surgery.

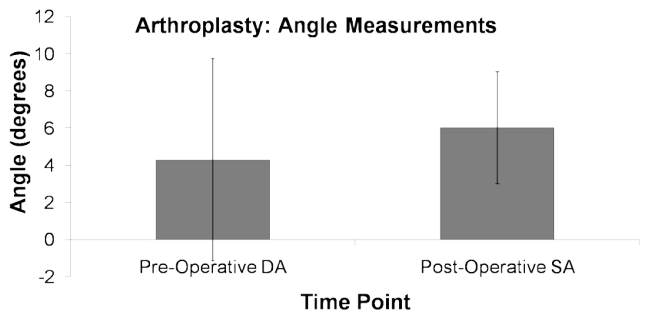

Figure 5: The mean pre-operative DA was 4.28 ± 5.45°. At mean of 18 months follow-up, the average SA of the Synergy Disc was maintained at 6 ± 3° of lordosis. The lordosis at the index level increased significantly p = 0.007.

Discussion

The Synergy Disc is differentiated by its variable lordotic core offerings and design goals to correct pre-operative deformity and maintain cervical lordosis. Our pilot results demonstrated physiological ROM with a maintained 6° of lordosis in the implant at a mean of 18 month post-surgical follow-up. In 17 Synergy cases, there was pre-operative parallel or a focal reducible kyphotic segment. The 6° Synergy Disc provided 6 ± 3° of lordosis to the surgical level in the patient cohort, providing physiological motion and alignment at the index level.

Preservation or the correction of cervical alignment has become an important and recognized goal in cervical spine surgery [8,9]. Degenerative disc disease is characterized by deterioration and collapse of the intervertebral disc accompanied by alterations of the spinal curvature [2]. Shim et al. reported a pre-operative disc angle (at index level) to be -0.7° (n=47 patients) in patients presenting with symptomatic degenerative disc disease [10]. Fong et al. studied 10 patients undergoing Bryan cervical disc arthroplasty and found that 40% had pre-operative angles between 1-2° lordosis and 30% were straight (parallel with 0°) [11]. Similarly, Johnson et al. studied 13 patients with a mean pre-operative angle of 1° and noted that the symptomatic segment was kyphotic because of a loss of anterior DH [12]. In a larger series (n=242), Takeshima et al. described 22% of DDD patients having a straight spine and 43% having a kyphotic angulation [13]. Traditional fusion strategies have incorporated techniques for restoration of appropriate cervical alignment [2,13,14]. Harrison et al. studied 252 asymptomatic subjects and found that the average lordosis between cervical vertebrae was between 6 and 7 degrees [15]. For the Synergy patients, despite a mix of parallel, kyphotic and lordotic DA, the mean post-operative SA was 6 ± 3°.

Although the initial design specifications of a cervical disc replacement was the maintenance of motion, concerns regarding cervical alignment have increasingly become prevalent in the literature [9,11,12,16]. Pickett et al. was the first to report a loss of lordosis (mean of 6°) at the surgical level following insertion of the Bryan cervical disc [9]. In a larger combined series, Pickett et al. found that 49% of inserted artificial discs (n=96) demonstrated varying degrees of kyphosis on lateral neutral radiographs [17]. Kim et al. found only 36% of patients with a pre-operative lordotic alignment was able to maintain lordosis following surgery [16]. Although no studies have specifically looked at cervical disc replacement kyphosis and neck pain, studies involving cervical fusion have reported new onset of axial symptoms and accelerated ASD related to segmental kyphosis at the surgical level [2,18]. Design limitations and technical nuances may contribute to the poor results in segmental alignment reported with some current cervical disc replacements [19,20]. Factors such as neck positioning in extension, overdrilling, and asymmetry of vertebral endplates, angle of disc insertion, pre-existing kyphosis and the structural absence of lordosis incorporated into the device have been implicated in the development of post-operative kyphosis [11,16,21]. As stated by Kim et al., "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" [16]. In our pilot of 37 patients, no cases of post-operative kyphosis were encountered. Neck pain, which is commonly associated with post-operative kyphosis, was negligible as demonstrated by the VAS neck pain scores [18]. In a

retrospective study by Tracey et al., single level cervical disc arthroplasty was compared with single level anterior discectomy and fusion [22]. In this cohort of 259 patients, the arthroplasty group (n=171) had a 15.8% (n=27 patients) rate of persistent neck pain, whereas the fusion group had a 12.5% (n=11 patients) rate of pain. Although the authors did not describe alignment measures for both groups, it is possible that the rates of reported neck pain were related to post-operative sagittal alignment.

Previous studies have demonstrated that the ProDisc-C had a slightly lordotic SA of 1.1 ± 3.6°, with 15% of patients demonstrating worsening kyphosis and 15% demonstrating hyperlordosis [5]. Similar studies by Anakwenze et al. and Ahn et al. suggest that the ProDisc-C can provide a modest increase in lordosis at the index level [23,24]. Rabin et al., however, demonstrated that a lordotic configuration of ProDisc-C endplates at the surgical level was associated with restricted segmental ROM and translation from neutral to extension [25]. Similar to other ball-and-socket disc replacements, the ProDisc-C was not designed to actively correct sagittal alignment. Du et al. recently described early clinical results with the Discover Cervical Disc (DePuy Spine, Raynham, MA, USA) [26]. The Discover disc incorporates 7° of lordosis evenly distributed in the device endplates, requiring precise endplate preparation and sculpting to receive the prosthesis [26]. Despite the lordotic endplates, however, the Discover disc has been reported to assume a kyphotic orientation [26]. It remains to be seen whether incorporation of lordosis into the endplates and polyethylene core are equally effective in preserving and/or correcting pre-operative sagittal balance.

The Synergy Disc maintained 9.8 ± 4.2° ROM, which is comparable with other devices (Figure 3) [3,5]. The DH at the index level following insertion of the 5 mm device was 37% greater than the pre-operative DH of to 3.5 mm. Garcia et al., CSRS 2006, suggested that overstuffing of the disc space may lead to decreased ROM, without any significant improvement in foraminal height [27]. The Synergy Disc provided pure translation, with no significant change in translation demonstrated between pre and post-operative radiographs. Following insertion of the device, there was an insignificant change in COR X values but a significant 1.3 mm superior shift in the COR Y value. The clinical consequences of shifting the COR by 1.3 mm remain unknown.

Juhl et al. reviewed asymptomatic individuals and found only 60% of individuals had a preserved cervical lordosis, while 19% and 21% had either a straight or kyphotic curvature, respectively [28]. In our previous experience with existing devices, patients with pre-operative parallel or kyphotic segments had an unpredictable, unacceptably high risk of worsening of kyphosis following cervical arthroplasty. As such, the indication for cervical arthroplasty in our practice and in the literature has progressively narrowed, excluding patients without a normal pre-operative cervical alignment at the index level [4]. This is reflected in our selection bias for arthroplasty cases, with the mean pre-operative DA for the Synergy group being 4.28 ± 5.45°. In our small pilot study, however, the Synergy Disc did provide acceptable lordotic correction in patients with pre-operative straightening or a focal, reducible kyphosis (Figures 4). Alignment incorporating disc replacements may present an opportunity to improve sagittal alignment and potentially expand the indication for cervical arthroplasty.

Study limitations

The goal of this pilot, feasibility study was to determine if the Synergy Disc could provide predictable sagittal alignment at the surgical level. As such, this study was not designed to randomize patients into a control arm with either fusion or an existing cervical disc replacement that does not actively correct sagittal deformity.

Software analysis of *in vivo* kinematics can be limited by patient factors. Out-of-plane motion, pain and patient effort may introduce variability over sequential films. Body habitus may obscure anatomical detail in the caudal segments of the cervical spine and contribute to error within all kinematic measures [3]. This study addresses only flexion/extension ROM and does not characterize the biomechanical behavior of the Synergy Disc in axial rotation or lateral bending. Analyzing patients after the first 6 months theoretically decreases the influence of post-operative pain and patient's discomfort on overall sagittal motion, allowing the cervical prosthesis to settle and the muscles and facet joints to adapt. In a 5-year retrospective study on cervical arthroplasty by Ryu et al., they found little long-term change in kinematic parameters, including SA, after the 12 months follow-up period [7]. Further follow-up in the Synergy patient group is needed to address the durability of sagittal alignment correction and the long-term clinical outcomes.

Summary

Concerns regarding the preservation and restoration of cervical alignment have become increasingly prevalent in the literature. This *in vivo* pilot study demonstrated that the Synergy Disc provided lordotic alignment to the surgical level while adequately maintaining ROM. The Synergy Disc was used successfully in patients with pre-operative parallel and kyphotic segments.

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