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Özgün Klinik Araştırma

Changes in Sagittal Alignment After Cervical Disc Arthroplasty: Results of 24-Month-Pilot Study

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Background Context: *For cervical disc replacements to be comparable to the gold standard of cervical discectomy and fusion (ACDF), disc replacements they must be able to provide normal range of motion as well as predictable and reliable correction of cervical alignment. The Synergy Disc was designed to provide correction of alignment in the sagittal plane while restoring physiologic range of motion.*
Purpose: *This study evaluated whether the Synergy Disc provided preservation and/or restoration of sagittal alignment while normalizing kinematics and providing acceptable clinical outcomes. The alignment provided by the Synergy Disc was compared with a retrospective cohort of 30 single- level ACDF patients.*
Study Design/Setting: *The pilot trial was a multi-center, prospective, consecutive patient enrollment study using the Synergy Disc for the treatment of single and two-level degenerative disc disease of the cervical spine.*
Patient Sample: *The procedure was performed on 43 patients (45 implants) with follow-up on 40 patients (42 implants). For the historical cohort ACDF arm, 30 patients with similar follow-up with single level anterior discectomy, fusion and plating were used for segmental lordosis measurements.*
Outcome Measures: *For the Synergy Disc group, the kinematic outcome parameters included: range of motion (ROM), shell angle (SA), disc height (DH), sagittal plane translation and center of rotation (COR) in the X and Y direction. Standard assessments of clinical outcomes were also measured (Neck Disability Index, Visual Analog Scale). For the fusion arm, only functional spinal unit (FSU) angle was recorded using a single preoperative and postoperative standing lateral cervical radiograph.*
Methods: *In the Synergy Disc group, static and dynamic radiological assessments were performed in 43 consecutive patients prior to the placement of the Synergy Disc. Forty patients were studied for the course of the study protocol (3 patients lost to follow-up). For the Synergy Disc group, lateral cervical radiographs were evaluated for range of motion, translation, center of rotation, disc height and shell angle before and at the longest postoperativr follow-up. Neck Disability Index and Visual Analog Scale for arm and neck pain were collected and analyzed. For the fusion group, standing lateral radiographs were reviewed.*
Results: *In all the patients (40 patients, 42 implants), followed up for at least 24 months at an average of 28 months the average SA of the Synergy Disc was maintained at 6±2.7° of lordosis. Preoperative ROM, translation and center of rotation on X axis did not change significantly following surgery. There was a significant upward shift in the center of rotation on Y axis. There was significant improvement in all clinical outcome measures. In the fusion group, with a similar follow-up period, there was a 4° increase in lordosis at the FSU.*
Conclusions: *The Synergy Disc provided lordosis at the surgical level, while maintaining preoperative range of motion, translation and COR X. The lordosis of 6±2.7° provided by the Synergy Disc at 2 years following surgery was comparable to the lordotic correction provided by an anterior cervical discectomy with interbody fusion and plating.*

Keywords: Sagittal balance, kyphosis, cervical arthroplasty, cervical sagittal alignment, synergy disc, kinematics, center of rotation, artificial disc

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Servikal Disk Artroplastisinden Sonra Sagital Dizilimdeki Değişiklikler: Yirmi Dört Aylık Pilot Çalışmanın Sonuçları

Arka Plan İçeriği: *Servikal disk replasmanlarının altın standart olan servikal diskektomi ve füzyonla (ACDF) karşılaştırılabilir düzeyde olması için disk replasmanları hem normal hareket erimi (ROM) hem de servikal dizilimde öngörülebilir ve güvenilir bir düzelme sağlayabilmesi gerekir. Fizyolojik hareket açıklığını sağlarken sagital düzlemde dizilimi düzeltmek üzere Synergy Disc tasarlanmıştır.*
Amaç: *Bu çalışma, Synergy Disc'in kinematiği normalleştirip kabul edilebilir klinik sonuçlar sağlarken, sagital düzlemde dizilimi düzelttiği ve/veya koruyup koruyamadığını değerlendirmiştir. Synergy Disc ile sağlanan dizilim 30 adet tek seviyeli ACDF uygulanmış bir retrospektif kohortunkiyle karşılaştırılmıştır.*
Çalışma Tasarımı/Ortamı: *Bu çalışma servikal omurganın tek ve iki seviyeli dejeneratif disk hastalığının tedavisinde Sinergy Disc'in kullanıldığı çok merkezli, prospektif ardışık hasta katılımlı bir pilot çalışma idi.*
Hasta Evreni: *Kırk üç hastanın (45 implantla) katıldığı, 40 hasta (42 implantın) takip edildiği bir uygulama yapılmıştır. Retrospektif kohort olan ACDF kolunda, segmental lordoz ölçümleri için tek seviyeli anterior diskektomi, füzyon ve plakla tespit yapılmış benzer takip süreli 30 hasta mevcuttu.*
Sonuç Ölçümleri: *Synergy Disc grubu için kinematik sonuç ölçümleri, hareket açıklığı (ROM), kabuk açısı (SA), disk yüksekliği (DH), sagital planda kayma (translasyon), X ve Y eksenlerinde dönme merkezini (COR) içermiştir. Klinik sonuçların standart ölçümleri de yapılmıştır (Örn. Boyun Disabilite İndeksi, Görsel Analog Ölçeği). Füzyon yapılan çalışma kolunda ameliyat öncesi ve sonrası ayakta çekilen tek bir servikal radyogramda yalnızca fonksiyonel spinal birim açısı (FSU) kaydedilmiştir.*
Yöntemler: *Synergy Disc grubunda, Synergy Disc yerleştirilmeden önce 43 ardışık hastada statik ve dinamik radyolojik değerlendirmeler yapılmıştır. Çalışma protokolü sürecinde 40 hasta çalışılmıştır (3 hasta takibe gelmemiştir). Synergy Disc grubunda hareket açıklığı, dönme merkezi, disk yüksekliği ve kabuk açısı için hem ameliyat öncesinde hem de postoperatif en uzun takipte lateral servikal radyogramlar değerlendirilmiştir. Kol ve boyun ağrısı için Boyun Disabilite İndeksi ve Görsel Analog Ölçeği puanları toplanmış ve incelenmiştir. Füzyon grubunda ayakta çekilen lateral radyogramlar gözden geçirilmiştir.*
Bulgular: *En azından 24 ay izlenen hastaların tümünde (40 hasta, 42 implant) ortalama 28 ayda Synergy Disc'in ortalama kabuk açısı (SA) 6±2.7° lordozda sabitlenmiştir. Cerrahi sonrasında ameliyat öncesi hareket açıklığı, translasyon ve X ekseninde dönme merkezi anlamlı derecede değişmemiştir. Dönme merkezinde Y-ekseninde anlamlı derecede yukarıya doğru yer değişimi olmuştur. Tüm klinik sonuç ölçümlerinde önemli bir iyileşme meydana gelmiştir. Benzer takip dönemli füzyon grubunda spinal birim açısında lordozda 4o artış olmuştur.*
Sonuçlar: *Synergy Disc, preoperatif hareket açıklığını, translasyon ve X-ekseninde dönme merkezini koruyarak cerrahi düzeyde lordoz sağlamıştır. Cerrahiden 2 yıl sonra Synergy Disc ile sağlanan 6±2.7° lordoz, intervertebral füzyon ve plakla fiksasyonla birlikte uygulanan anterior servikal diskektomiye karşılaştırılabilir düzeydeydi.*

Anahtar kelimeler: Sagital denge, kifoz, servikal artroplasti, servikal sagital dizilim, synergy disc, kinematik, dönme merkezi, yapay disk

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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 sagittal balance 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 provides controlled alignment correction in the sagittal plane while restoring physiologic range of motion (ROM). The Synergy Disc has a titanium-on-polyethylene articulation with a mobile center of rotation (COR) and varying degrees of alignment correction incorporated into the polyethylene core (Figure 1).

The kinematic outcome of a small subset of single level Synergy Disc patients has 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 2-year results of the Synergy cohort to determine if it can provide a sagittal alignment correction comparable to ACDF.

MATERIALS AND METHODS

Patient population

Forty-three consecutive patients with objective clinical and radiographic evidence of DDD causing refractory radiculopathy and/or myelopathy were prospectively enrolled in this pilot safety study with Synergy Disc insertion. 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.

Patient Selection Criteria

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. Pre-operative radiographs exhibiting only single-level or 2-level DDD were included in this study. Ten patients

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

had pre-operative straightening of the cervical spine, while eight patients had a reducible kyphosis. The remaining 22 patients demonstrated a pre-operative cervical lordosis. Exclusion criteria included previous cervical spine surgery, trauma, active infection, osteoporosis, multilevel spondylotic disc degeneration and radiographic signs of instability. 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. The posterior longitudinal ligament was divided in all cases. Under fluoroscopy monitoring, the device was inserted.

For the retrospective fusion arm, 14 patients had a normal pre-operative lordosis, 10 had pre-operative straightening of the cervical spine, and 6 had focal kyphosis at the surgical level.

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 at the 1.5, 3, 6, 12 and at 24-months post-operatively.

Radiographic Analysis

For the Synergy Disc arm, independent prospective x-ray analysis of 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 to assess device kinematics and alignment. Validated radiographic Quantitative Motion Analysis (QMA) software (Medical Metrics, Inc., Houston, TX), was used to analyze 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.

For the fusion arm, the FSU was retrospectively calculated by an independent observer on 3 separate occasions for each radiograph and averaged to ensure accurate measurement of the FSU angle.

Synergy Disc Description

The Synergy Cervical Disc is a MRI prosthesis made with a titanium-on-polyethylene articulation, with a mobile COR and varying degrees (0° and 6°) of lordotic correction incorporated into 5-6 and 6-7 mm height devices. The sagittal and coronal alignment control is incorporated into the polyethylene. Fully coupled ROM is possible. The insertion technique is ACDF-like, incorporating a lordosis trial before insertion of the device. For this pilot study, 6° lordotic cores with a 5-6 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

SYNERGY DISC GROUP

Patient population

Forty patients (38 patients with 1-level and 2 patients with 2-level) were assessed at a minimum

of 24 months following surgery. The mean age was 45.8 years (22 males and 18 females). Three patients did not have the required minimum 24 month follow-up evaluation and were excluded. The 3 excluded patients, however, they 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 5-6 mm height. There was immediate relief of radiculopathy and/or myelopathy in all cases, with no complications related to the surgical approach, instrumentation or the device. No explantations or reoperations were performed and no delayed device complications including migration, subsidence, fusion or heterotopic ossification as identified by lateral radiographs was encountered at any time-points in the follow-up period.

Clinical Outcomes

There was a significant improvement in the mean VAS neck pain score at the last follow-up (8.2±1.0 pre-operatively vs. 0.5±0.5 post-operatively, $p<0.05$). Similarly, mean VAS arm pain scores improved significantly (7.9±0.6 pre-operatively vs. 0 post-operatively, $p<0.05$). Over the 24 month period, mean NDI scores also improved significantly (4.1±0.8 pre-operatively vs. 1±0.2 post-operatively, $p<0.05$).

Radiographic Outcomes

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 24 months the average SA of the Synergy Disc was 6±2.7° of lordosis. There was a significant increase in lordosis at the index level $p= 0.007$. There were no cases of post-operative kyphosis.

ROM was maintained at the index level 24 months following surgery (12±5.2° pre-operatively vs. 9.7±4.2° post-operatively; $p>0.05$; Figure 2). Pre-operatively, the mean DH was 3.5±0.8 mm. Following insertion of the 5-6 mm Synergy Disc, the DH increased significantly (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. 1.6±1.2 mm post-operatively,

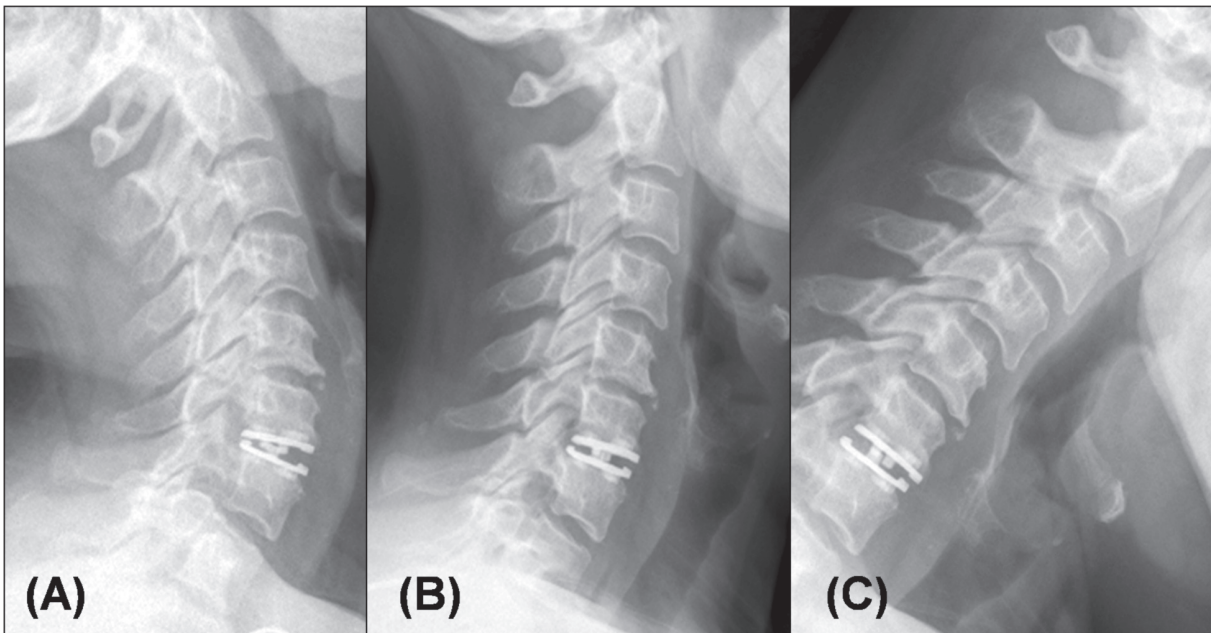

Figure 1. Extension (A), neutral (B) and flexion (C) lateral radiographs 24 months following insertion of Synergy Disc demonstrating 13.9 degrees of ROM from extension to flexion and an upright (B) disc angle of 6.7 degrees of lordosis in neutral.

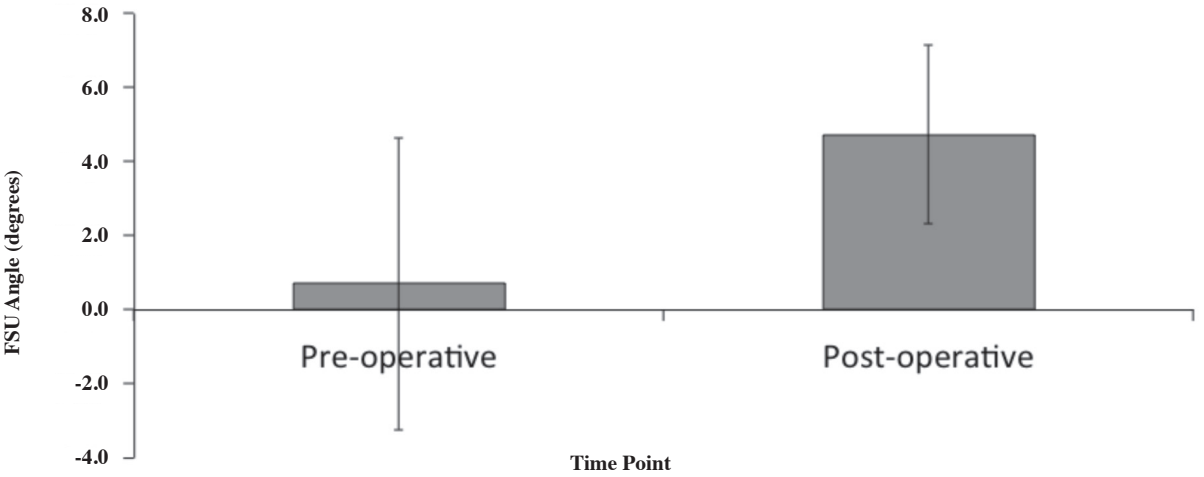

Figure 3. In the ACDF group, the pre-operative Functional Spinal Unit (FSU) angle measurement at the index level was 0.71± 3.95°. At, the FSU angle increased to 4.74± 2.42°, representing a significant increase in lordosis at the surgical level, p<0.05. Error bars represent standard deviation.

p>0.05). Similarly, COR X remained unchanged (-0.8±0.9 mm pre-operatively vs. -0.3±0.7 mm post-operatively, p>0.05) while a superior shift occurred in COR Y (3.8±2.3 mm pre-operatively vs. 2.3±2.4 mm post-operatively; p<0.05).

FUSION GROUP

Thirty patients with single level ACDF were retrospectively reviewed for FSU angle measurements pre and a mean of 19 months post ACDF. The pre-operative FSU angle measurement at the index level was 0.71±3.95°. Following surgery, the FSU angle increased to 4.74±2.42°, representing a significant increase in lordosis at the surgical level, p<0.05 (Figure 3). Post-operatively, 27 patients demonstrated lordosis at the surgical level, with only 3 cases of a parallel configuration at the surgical level.

DISCUSSION

The Synergy Disc is unique by its variable lordotic core, designed to correct pre-operative sagittal alignment and maintain cervical lordosis. Our pilot results demonstrated physiological ROM with a maintained 6° of lordosis in the implant at 24 months post-surgical follow-up. In 18 Synergy cases, there was pre-operative straightening of the cervical spine or a focal reducible kyphotic segment. The 6° Synergy Disc provided 6±2.7° of lordosis to the surgical level in all patients. To relate the lordosis correction of the Synergy Disc with the gold standard, we retrospectively collected 30 ACDF cases with comparable follow-up and analyzed the FSU for this retrospective series of fusion cases. Both the Synergy Disc and ACDF provided improved sagittal balance post surgery.

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 [8,10,11,15]. Pickett et al. initially reported a loss of lordosis (mean of 6°) at the surgical level following insertion of the Bryan cervical disc [8]. 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 [16]. Kim et al found only 36% of patients with a pre-operative lordotic alignment were able to maintain lordosis following surgery [15]. Although no studies have specifically looked at cervical disc replacement kyphosis and neck pain, studies involving cer-

vical fusion have reported new onset of axial symptoms and accelerated ASD related to segmental kyphosis at the surgical level [2,17]. Design limitations and technical nuances may contribute to the poor results in segmental alignment reported with some current cervical disc replacements [18,19]. Factors such as neck positioning in extension, overdrilling, 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 [10,15,20]. 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 [15]." In our pilot, 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 [17]. In a retrospective study by Tracey et al., single level cervical disc arthroplasty was compared with single level anterior discectomy and fusion [21]. 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±3.6º, 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 [22,23]. 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 [24]. 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) [25]. The Discover disc incorporates 7º of lordosis evenly distributed in the device endplates, requiring precise endplate preparation and sculpting to receive the prosthesis [25]. Despite the lordotic endplates, however, the Discover disc has been reported to assume a kyphotic orientation [25]. 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.

Preservation or the correction of sagittal balance in the cervical spine has become an important and recognized goal in cervical spine surgery [7,8]. DDD 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 [9]. 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°) [10]. 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 [11]. In a larger series (n=242), Takeshima et al. described 22% of DDD patients having a straight spine and 43% having a kyphotic angulation [12]. Traditional fusion strategies have incorporated techniques for restoration of appropriate sagittal balance [2,12,13]. Harrison et al. studied 252 asymptomatic subjects and found that the average lordosis between cervical vertebrae was between 6 and 7 degrees [14]. In our study, for the fusion group, the pre-operative FSU angle measurement at the in-

dex level was 0.71±3.95°, consistent with loss of anterior disc height and paralleling of the vertebral endplates associated with disc degeneration. Following surgery, the FSU angle increased to 4.74±2.42°, representing a significant increase in lordosis at the surgical level, $p<0.05$. For all fusion cases, lordotic allograft and cervical plates were utilized. For the Synergy group, the mean pre-operative DA was 4.28±5.45°. Following disc replacement, the SA demonstrated 6±2.7° of lordosis. Hence, both ACDF and the Synergy Disc provided an increase in lordosis at the surgical level.

The Synergy Disc maintained ROM comparable to other devices [3,5]. The DH at the index level following insertion of the 5-6 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 [26]. 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 [27]. 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 lordosis [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° and the preoperative FSU angle for the fusion group being 0.71±3.95°. Given this bias, we did not directly compare the groups. 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, much like an ACDF. 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 a predictable impact on 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 may 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 any of the devices 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 6 months follow-up period [28]. Because it is impossible to assess DA following fusion, the ACDF group had FSU angle measurements. Further follow-up in the Synergy patient group will address the durability of sagittal alignment correction and the long-term clinical outcomes.

Summary

Concerns regarding the preservation and restoration of cervical sagittal balance have become increasingly prevalent in the literature. This in vivo pilot study demonstrated that the Synergy Disc provided predictable lordotic alignment as did ACDF.

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