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Araştırma / *Research Article*

Long-Term Functional and Symptomatic Outcomes of Cervical Disc Prostheses

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Servikal Disk Protezlerinin Uzun Dönem Fonksiyonel ve Semptomatik Sonuçları

ABSTRACT

Objective: *Cervical disc arthroplasty aims preservation of motion at the operated level while minimizing degenerative disease at adjacent levels. This study aimed to examine the long-term functional outcomes of patients with cervical disc pathology who were operated with arthroplasty technique.*
Method: *Sixty-eight patients who underwent cervical disc prosthesis implantation for disc herniation or spondylosis were included. Functional outcomes over time were evaluated using Neck Disability Index (NDI) and visual analogue scale (VAS) at baseline and 6 months, 1 year, 2 years, 4 years and 7 years after surgery.*
Results: *Mean duration of follow-up was 5.4±1.8 years (median, 7 y; range, 1-7 y). At the last follow-up visit, VAS and NDI scores were significantly lower compared to baseline (1.2±0.9 vs. 7.7±1.2, p<0.001 and 5.5±5.0 vs. 40.4±5.8, p<0.001, respectively). VAS and NDI scores were improved at all measured time points compared to baseline (p<0.001 for all comparisons). A plateau was reached at 2 years and at 1 year for VAS and NDI scores, respectively. The overall predefined surgical success rate was 86.8% at the last follow-up.*
Conclusion: *Findings of this study supports the benefit of cervical dynamic disc systems in cervical disc surgery in terms of functional outcomes both in the short-term after surgery and in the long term.*

Keywords: *cervical disc degeneration, cervical disc prosthesis, cervical disc arthroplasty, long-term follow-up, functional outcomes*

ÖZ

Amaç: *Servikal disk artroplastisi, komşu seviyelerde dejeneratif hastalığı en aza indirirken, ameliyat edilen seviyede hareketin korunmasını amaçlamaktadır. Bu çalışmada artroplasti tekniği ile opere edilen servikal disk patolojisi olan hastaların uzun dönem fonksiyonel sonuçları araştırıldı.*
Yöntem: *Disk hernisi veya spondiloz nedeniyle servikal disk protezi implantasyonu yapılan 68 hasta çalışmaya dahil edildi. Zaman içindeki fonksiyonel sonuçlar Boyun Özürlülük İndeksi (NDI) ve görsel analog skalası (VAS) kullanılarak başlangıçta ve ameliyattan 6 ay, 1 yıl, 2 yıl, 4 yıl ve 7 yıl sonra değerlendirildi.*
Bulgular: *Ortalama takip süresi 5.4 ± 1.8 yıl (ortanca, 7 y; aralık, 1-7 y). Son takip VAS ve NDI skorları anlamlı derecede düşüktü (sırasıyla 1.2±0.9-7.7±1.2, p<0.001 ve 5.5±5.0-40.4±5.8, p<0.001). VAS ve NDI skorları ölçülen tüm zaman noktalarında düzeldi (tüm karşılaştırmalar için p<0.001). VAS ve NDI skorları için sırasıyla 2 yılda ve 1 yılda bir platoya ulaşıldı. Cerrahi başarı oranı son takipte % 86.8 idi.*
Sonuç: *Bu çalışmanın bulguları, servikal disk cerrahisinde servikal dinamik disk sistemlerinin hem cerrahi sonrası kısa dönemde hem de uzun vadede fonksiyonel sonuçlar açısından faydasını desteklemektedir.*

Anahtar kelimeler: *servikal disk dejenerasyonu, servikal disk protezi, servikal disk artroplastisi, uzun süreli takip, fonksiyonel sonuçlar*

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INTRODUCTION

Symptomatic degeneration of cervical disc presents with neck pain radiating to arm and sensory or motor deficit. Depending on socioeconomic factors, one-year prevalence ranges between 12.1% to 71.5% (37.2% in average); thus cervical disc degeneration represents an important disease burden with associated disability [1].

Mostly, the disc recovers itself with conservative treatment without necessitating surgical intervention. Usually conservative treatment consists of analgesics and anti-inflammatory drugs, steroids, opioids, and myorelaxants as well as cervical collar use, physical therapy and massage. In addition, chiropractic treatment, passive and active modalities, spinal steroid injections; and even alternative treatments are used. Soft disc herniations should be followed by conservative treatment initially for about 6 weeks. Diffuse disc herniations respond to conservative treatment better than focal type herniations [2]. Surgery is an effective and valid option when conservative treatment fails [3-6] and its timing depends on the severity of symptoms and neurological deficit or neurological deficit potential.

Anterior decompression of the disc with or without interbody cage has been performed for the cervical pathologies causing myelopathy and radiculopathy with the aim of obtaining fusion after discectomy at the operated level [7-12]. Although this surgical technique generally results in success, many disadvantages have been reported [13,14], prompting surgeons to discover alternative methods, such as cervical disc arthroplasty, which aims preservation of motion at the operated level while minimizing degenerative disease at adjacent levels [15,16].

Neck Disability Index (NDI) and visual analogue scale (VAS) are two simple and reliable scales for symptomatic follow up. They allow for the evaluation of functional improvements as well as complications.

This study aimed to analyze the long-term functional outcomes as assessed by NDI and VAS in patients with cervical disc pathology who were operated with arthroplasty technique.

MATERIAL and METHODS

Patients

A total of 68 patients who underwent cervical disc prosthesis implantation between January 2009 and November 2018 in our institution were included. The indication for prosthesis implantation was disc herniation or spondylosis at one or two levels that has failed to respond conservative therapies for at least 6 weeks. All levels between C3-4 and C7-T1 were included and all patients were required to have intact and functional posterior elements such as facets and ligaments. Exclusion criteria were as follows: pregnancy, rheumatoid diseases, previous cervical fractures with ligamentous or facet injury, metabolic or systemic diseases, malignancies, metal allergy, local or systemic infection, severe osteoporosis, spinal cord compression by the vertebral corpus, radiologically confirmed facet joint pathology, cervical kyphosis, cervical spondylolisthesis or severe cervical spondylosis. Patient characteristics are shown in Table 1.

Table 1. Implantation levels, prosthesis types and surgical success rate.

Characteristic	n (%)
Implantation level	
C 3-4	1 (1.5%)
C 4-5	1 (1.5%)
C 5-6	32 (47.1%)
C 6-7	21 (30.9%)
Multiple levels	13 (19.1%)
Prosthesis type	
NUNEC®	4 (5.9%)
PRESTIGE®	33 (48.5%)
BRYAN®	10 (14.7%)
PSM®	21 (30.9%)
Overall surgical success*	59 (86.8%)

Unless otherwise stated, data presented in number (percentage)
** All following conditions had to be met at the last follow-up visit: VAS score ≤5, at least 20% improvement in NDI score compared to baseline, and absence of any reoperation, device removal and complication*

Four patients were implanted with Nunec, 10 patients with Bryan (Fig. 1), 21 patients with PCM (Fig. 2) and 33 patients with Prestige (Fig. 3) prostheses.

Preoperative assessments

All patients underwent preoperative radiological studies of the cervical spine including X-rays (anteroposterior, lateral, flexion/extension views), computed tomography (CT) and MRI including T1 and

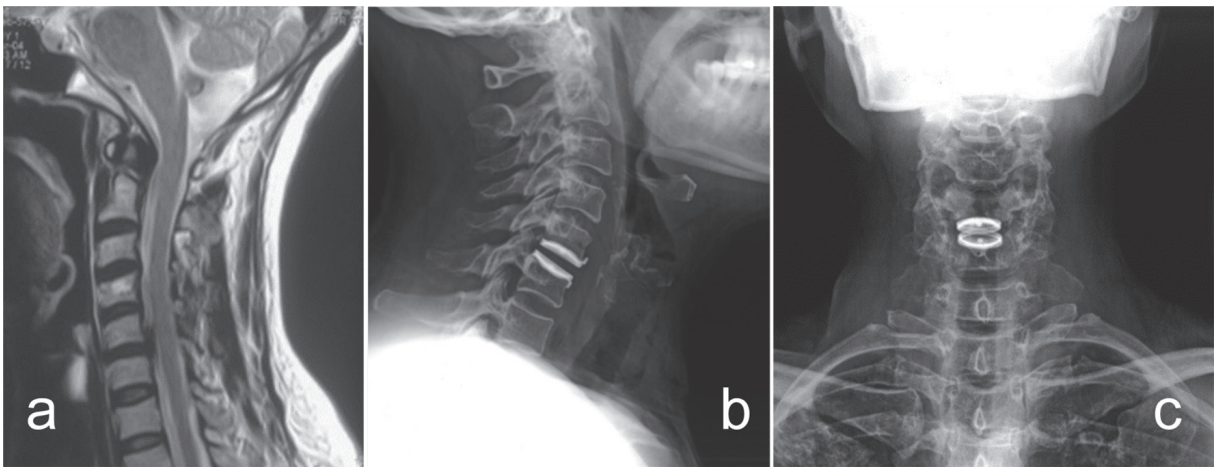

Figure 1. Preoperative MRI (a) and postoperative x-rays (b, c) of a patient with Bryan disc prosthesis.

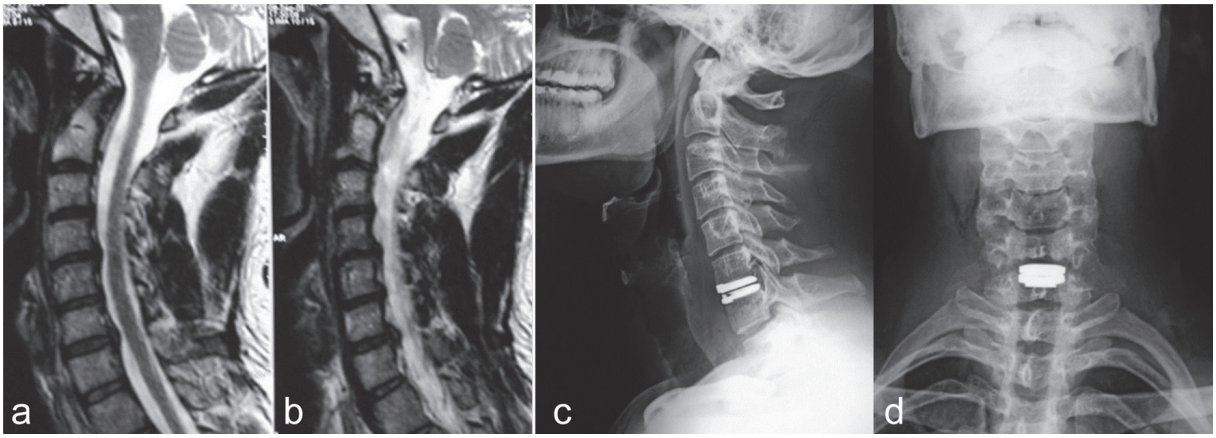

Figure 2. Preoperative MRI (a, b) and postoperative x-rays (c, d) of a patient with PCM disc prosthesis.

T2-weighted sequences in transverse and sagittal planes. Health-related quality of life of the patients was evaluated at baseline by using a visual analogue scale (VAS) for the self-assessment of neck and/or shoulder/arm pain, with scores ranging between 0 and 10 and Neck Disability Index (NDI). NDI is a reliable measure of the functional impact of the patients' neck discomfort [1]. It has 10 sections for the assessment of pain intensity, personal care, lifting, reading, headaches, concentration, work, driving, sleeping, and recreation. Immediately before surgery, patients were asked to complete the questionnaires for baseline measurements.

Postoperative assessments

The patients were evaluated at 6 months, 1 year, 2 years, 4 years and 7 years using VAS and NDI to evaluate changes over time. In addition, postoperatively, anterior posterior and lateral dynamic X-rays were obtained at each follow-up visit to see the position of the prostheses. Based on the last follow-up visit, a successful surgical outcome was defined as follows (all criteria had to be met): (i) VAS score ≤5; (ii) at least 20% NDI improvement from baseline; (iii) absence of reoperation, device removal, and prosthesis related major complication. All patients received physical therapy and rehabilitation program between 6 weeks to 6 months before and after surgery.

Surgical technique

All patients were operated by the same surgical team using the microsurgical technique. The patient was positioned in neutral or mildly lordotic neck position to select the appropriate prosthesis size. The neck was supported dorsally with a roll to keep lordosis and the targeted level was determined using C-arm fluoroscope. A right-sided standard Smith-

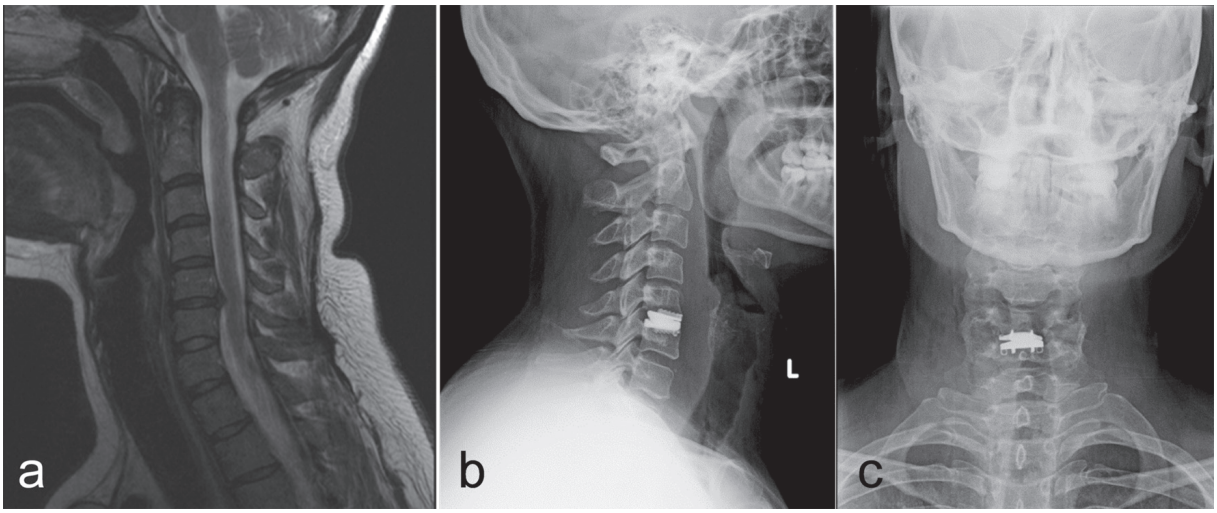

Figure 3. Preoperative MRI (a) and postoperative x-rays (b, c) of a patient with Prestige disc prosthesis.

Figure 4. Özer cervical retractor. Left, side view, right, upper view.

Robinson anterior cervical approach was through a transverse incision. The trachea, esophagus, and carotid artery were retracted to expose vertebral bodies and discs and the level was confirmed with fluoroscopy. Following dissection of the longus colli muscles, an Özer retractor (Fig. 4) was placed. After total discectomy, osteophytes were removed with the help of high-speed drill. Posterior longitudinal ligament was removed according to the discretion of the surgeon. Using the drill, end plates were made parallel, taking care not to disrupt them. The uncovertebral joints were removed bilaterally with generous foraminotomies.

The implant selection was done with the aid of trial spacers. Then the artificial disc was inserted into the prepared disc space, with the guide of fluoroscopy. Following the closure of platysma and skin incision, position of the prosthesis was confirmed using fluoroscopy.

Statistical analysis

Statistical Package for Social Sciences (SPSS) version 21 was used for the analysis of data. Descriptive data are presented as mean ± standard deviation, median (range) or frequency (percentage), as appropriate. Baseline and last follow-up visit scores were compared using student t test for paired samples. Changes in scores throughout the follow-up period were examined using one-way ANOVA for repeated measurements and Bonferroni adjusted p values were used for multiple comparisons. A p value <0.05 was considered an indication of statistical significance.

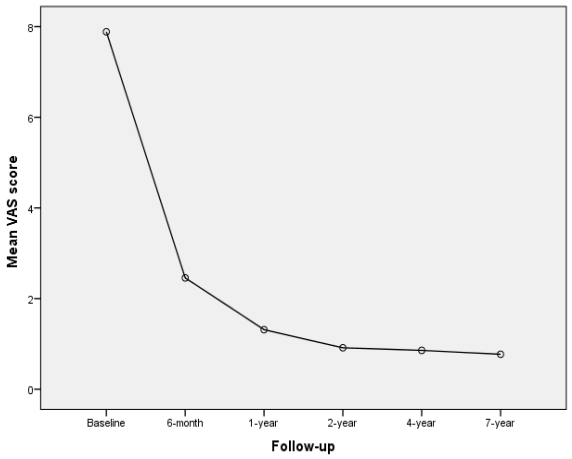

Figure 5. Changes in mean VAS scores during follow-up.

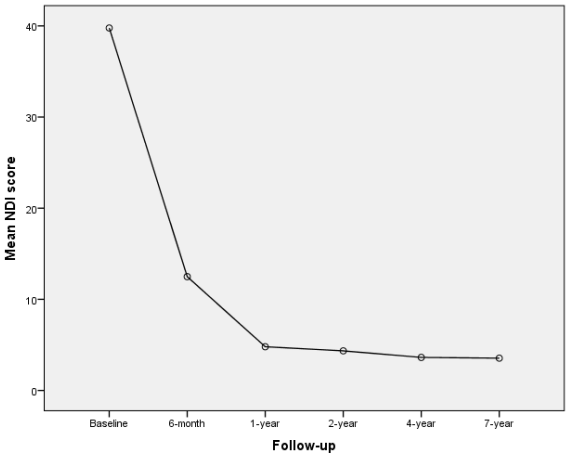

Figure 6. Changes in mean NDI scores during follow-up.

RESULTS

Patients

Among the 68 patients included, 35 were female and 33 were male. The mean age was 37.8±8.3 years (range 23-60 y). In most patients, implantation was performed at single level (80.9%). Most common sites were C 5-6 and C 6-7 for single level implantations, constituting 96.4% of the cases in this subgroup. Table 1 shows surgical details (implantation levels, prosthesis types and surgical success rate) of the study group.

Changes in NDI and VAS scores at the last follow-up visit

Mean duration of follow-up was 5.4±1.8 years (median, 7 y; range, 1-7 y). At the last follow-up visit, mean VAS score was significantly lower compared to baseline (1.2±0.9 vs. 7.7±1.2, p<0.001). Similarly, a significant reduction was observed in NDI scores compared to baseline (5.5±5.0 vs. 40.4±5.8, p<0.001).

Significant changes occurred in VAS and NDI scores throughout the study period (p<0.001 for both) (Figures 5 and 6,). VAS scores were improved at all measured time points compared to baseline (p<0.001 for all comparisons). Following a sharp decrease at 6 months (p<0.001), VAS scores continued to improve until 2 years, after which they reached a plateau (p<0.001 for 1 year vs. 6 months and p=0.002 for 2 years versus 1 year). Similarly, NDI scores improved significantly at all measured time points compared to baseline (p<0.001 for all comparisons). However, a plateau was reached at 1 year for NDI scores (p<0.001 for 1 year vs. 6 months).

The overall predefined surgical success rate was 86.8% at the last follow-up. Prosthesis-related complications developed in five patients: two cases of prosthesis displacement, one insufficient decompression, one case with pain requiring fusion and 1 heterotopic ossification.

DISCUSSION

In this study patients that underwent cervical arthroplasty with disc prostheses at the same institution were followed for functional outcomes and dramatic improvements were obtained early after operation and functional improvements continued until 1 to 2 years until reaching a plateau. Four different types of prostheses were used in this study. We believe that this study is unique in terms of both remarkably long duration of follow-up and inclusion of patients that received different types of prosthesis.

Anterior cervical discectomy and fusion (ACDF) has been considered as the gold standard surgical technique for treating symptomatic cervical degenerative disc diseases (CDDD) since the 1950s [3]. Before the cage and anterior plate era discectomy alone was performed. Since cages can easily preserve disc height, restore cervical lordosis and prevent implant collapse, they became more popular than discectomy alone. Oktenoglu et al., compared discectomy alone and ACDF in patients with cervical disc disease and reported that ACDF was better than anterior cervical discectomy (ACD) in preserving the neural foraminal height at the operated level; however, this advantage disappeared as short as one year after the operation in some patients [17]. Similar results were

also reported by Thorell et al [18]. ACDF has been accepted to be a satisfactory surgical procedure for cervical spondylosis with myelopathy and/or radiculopathy caused by degenerative disc disease (DDD).

Robinson and Smith and later Cloward were the first to develop the technique of anterior cervical discectomy and fusion for cervical disc disease and spondylosis [15,19]. The clinical results were favorable, but the disadvantages of the procedure were the elimination of motion in a formerly mobile functional segment and hypermobility at adjacent segments, which caused increased strain in the adjacent segments resulting in further disc degeneration and instability [13,15]. Segments adjacent to fusion may have increased range of motion (ROM) and increased intradiscal pressure, causing recurrence of neurological symptoms and degenerative changes adjacent to the fused cervical levels [20]. Almost 25% of the patients have new symptoms within 10 years after ACDF [20]. Dimitrev et al. reported 48% and 12.5% increased intradiscal pressure at the proximal and distal adjacent levels during flexion and extension testing, respectively [21]. According to Hilibrand et al, adjacent level degeneration rate is 2.9% per year after anterior cervical discectomy and fusion, with an overall incidence of 25.6% within ten years [22]. Although these adjacent segment changes are not always associated with clinical symptoms, radiographic clues of spondylosis and instability have been discouraging [23]. Cervical disc arthroplasty (CDA) was developed to achieve similar neural decompression level with ACDF, to maintain segmental motion, and to reduce the incidence of adjacent segment degeneration (ASD) [7,8]. In the past decade, CDA was widely used and achieved satisfactory short- and mid-term outcomes for the treatment of CDDD; thus, it became an alternative to arthrodesis [7,8]. However, long-term outcomes of CDA need further evaluation. Moreover, it remains to be investigated whether, compared with ACDF, CDA can reduce the incidence of ASD in the long-term.

First paper about cervical arthroplasty was published in 1950 [24], but clinical application was after 2000's. Fernstrom, the inventor of lumbar disc prostheses, used spherical shaped devices. Although Reizt and Joubert reported satisfactory results [10], these devices have a high risk of steel ball subsidence to the vertebral corpuses eventually leading to fusion. Different alternative cervical discs have been invented since than such as Bryan, ProDisc-C, PCM, Prestige, Cervi Core, Mobi-C [15]. These different designs consist of either articulating or non-articulating components constructed from various materials. Material choice for a prosthesis is important to supply the needs of both the articulating surface and the interface between prostheses and vertebral body [25].

Following are the advantages of disc arthroplasty: less adjacent segment degeneration, maintenance of motion at the operated level, decreased surgical morbidity, avoidance of postoperative immobilization, and better reconstruction of disc height and spinal alignment [16]. Cervical disc arthroplasty aims motion preservation at the operated level while minimizing adjacent level degenerative disease through restoration of cervical motion at operated level by preserving the normal kinematics of the spine and by prevention of normal motion at the adjacent levels. The technique reconstitutes the space height, thus maintains the neural decompression and aims to maintain the stability at the operated level [15,20]. In addition, these devices do not complicate a subsequent fusion procedure if the arthroplasty fails and leads to a painful pseudarthrosis. Cervical arthroplasty systems have been found to be superior to ACDF in terms of secondary surgical interventions, postoperative biomechanical success, and neurological success [26,27]. In addition, radiographical degeneration of adjacent segments were more frequent after ACDF [28].

It has been documented that the conventional cervical surgical technique, namely ACDF surgery, causes improvements in NDI and VAS [29]. Some studies examined outcomes of fusion patients [30-34], whereas others compared fusion with arthroplasty [15,16,26,28,35-37]. Neck pain, arm pain and NDI generally show significant improvements during the follow-up of patients after ACDF [38]. These improvements are gradual underlining the long-term effectiveness of the procedure. For example, in the study of Buttermann et al., VAS for neck and arm pain diminished from 7.8 to 3.3 at the end of 10-year follow up in 159 patients operated at the same institution using ACDF technique [30].

According to Aragones et al., the improvements in NDI and VAS scores are significantly better with arthroplasty than with arthrodesis [29,37]. The results of Li et al. showed that although ACDR resulted in a

lower rate of adjacent segment degeneration and subsequent corrective surgeries in less than 7 years after the primary surgery, ACDR patients had similar NDI and VAS scores to those of ACDF [31]. In the study by Zeng et al. where 53 ACDF patients were compared with 45 ACDR patients, the VAS-neck and VAS-arm scores were similar across the groups; however, patients who underwent arthroplasty with Prestige-LP Discs showed more improvement in the NDI score [32]. In some studies, arthroplasty was apparently better even in case of implantation of contiguous 2-level degenerative disc disease [39]. Arthroplasty technique was effective and safe in the study by Gao et al [39], which found that it maintains physiologic motion at 5 years with satisfactory clinical outcomes and a relatively low occurrence rate and adjacent degeneration. On the other hand, there was no statistically significant difference between the disc prostheses and fusion groups in terms of VAS and NDI scores in several studies [31,33].

This study found dramatic amelioration of the symptoms starting early after surgery and continuing during the following years in patients that underwent arthroplasty. We believe that the reason of this favorable outcome can be well attributed to maintaining segmental motion and reducing the incidence of adjacent segment degeneration (ASD). However, this study does not have radiological follow-up, which may be considered a limitation.

In conclusion, the use of cervical dynamic disc systems in cervical disc surgery seems to be effective in terms of functional recovery both in the short- and the long-term.

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