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In vivo dynamic analysis of the bone–implant interface in cervical disc implants: a research article

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ABSTRACT

Aims: This study aimed to determine whether micro-motions occur at the bone–implant interface of UFO cervical disc prosthesis.

Methods: The sagittal range of motion of the functional spinal unit, which was defined as the angle formed by lines drawn at the superior margin of the upper vertebral body and the inferior margin of the lower body, was determined preoperatively and postoperatively. The presence of micro-motions at the bone-implant interface was also evaluated.

Results: We report the results of a dynamic computed tomography evaluation method to determine whether micro-motions occur at the bone–implant interface of cervical arthroplasty devices during the 1-year postoperative follow-up.

Conclusion: While significant motions could be observed in all our patients, in one level, significant (6°) segmental micro-motions at the bone–implant interface could be documented.

Keywords: Cervical disc disease, functional spinal unit, intervertebral disc prosthesis

INTRODUCTION

Anterior cervical discectomy with fusion is the gold standard in the surgical treatment of cervical degenerative disc diseases; however, a retrospective long-term study showed that approximately 3% of patients had adjacent-segment symptoms, with a predicted 10-year prevalence of approximately 25%, which is due to increased biochemical stresses and accelerated degeneration of neighboring spinal motion segments.[1] This novel concept of adjacent-segment disease is unproven, and the true incidence of this disease remains controversial. Moreover, little data in the literature support this theory.

The treatment of cervical spinal disorders is undergoing a paradigm change, from favoring fusion to motion preservation, since Goffin first reported treating cervical spondylotic radiculopathy with artificial cervical intervertebral disc prosthesis in 2002.[2] Artificial cervical intervertebral discs are intended to maintain the motion of the intervertebral space and theoretically slow down the degeneration of the adjacent space, allowing the restoration of the physiological curvatures and range of motion (ROM) of cervical vertebrae to the greatest extent possible. Intermediate follow-up studies, in which ROMs of the prosthesis were measured using dynamic plain X-ray images, have shown that cervical disc prostheses allow for the preservation of motions over time at index levels, and most of the adjacent segments are mobile.[3-6] Nevertheless, total cervical disc replacement (TCDR) is not free of complications. First, after the surgery, the normal mode of activity of the intervertebral space may not be restored. Specifically, the restoration of the transient axis of rotation when the cervical vertebrae are in motion is very challenging. In some cases, it may be impossible given that, after artificial cervical intervertebral disc replacement, the motion of the cervical vertebra is still unstable because of the asymmetric mechanical behavior between flexion and extension, probably due to the removal of the anterior longitudinal ligament and the preservation of posterior structures.[7] Second, although only a few reports about the radiologic outcomes following TCDR have been published thus far, heterotypic ossifications are responsible for the fusion of nearly 9% of the treated levels in these early follow-up studies, which leads to the suspicion of an even higher rate of spontaneous fusion after long-term follow-ups.[8,9] Third, because most of the artificial discs are not intended to restore lordosis, whether a preoperative kyphosis can be corrected while preserving motions remains unanswered. Given the passive design, most of

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the patients who underwent arthroplasty with cervical artificial discs experience a focal loss of lordosis following surgery at the treated levels, although the overall sagittal alignment can be maintained.[10-16] Finally, the degenerative conditions of the spine cause the sinking of the implant into the vertebral body.

Thus, this study aimed to determine whether micro-motions occur at the bone–implant interface of the cervical disc prosthesis.

METHODS

The study was carried out with the permission of Alanya Alaaddin Keykubat University Faculty of Medicine Clinical Researches Ethics Committee (Date: 02/03/2022, Decision No: 03-07). All procedures were carried out in accordance with the ethical rules and the principles of the Declaration of Helsinki.

An arthroplasty with the UFO artificial disc (Pao Nan Biotech, Taiwan) was considered the most suitable choice for our patients because of several factors: first, the preservation and, if possible, the restoration of motions in the affected cervical spine segments appeared to be achievable using a multiaxially mobile construct of silicone. Second, the easy application of the device saved a considerable amount of time. Third, the overall sagittal alignment and lordosis could be better maintained with an implant having a nearly spherical shape. The posterior longitudinal ligament was not cut, so we tried to restore the natural disc height and functional spinal unit angle (if kyphotic) intraoperatively using an intervertebral distractor (Figure 1).

Figure 1. Intervertebral distractor used to restore the natural disc height and functional spinal unit angle (if kyphotic) intraoperatively.

The mobility of the implanted segments must be studied in detail, and we think that this is a more complex and unreported issue when more than one single level is operated upon. For this study, we examined six multilevel spondylotic cases among our patients with TCDR 1 year after the surgery, one female and six male patients aged 40–62 years without any osteoporosis (Table 1). Two and four patients underwent two- and three-level surgery, respectively. The sagittal ROM of the functional spinal unit, which was defined as the angle formed by lines drawn at the superior margin of the upper vertebral body and the inferior margin of the lower body, was determined preoperatively and postoperatively. Fine spiral computed tomography (CT) section of flexion and extension of the median sagittal plane were used for these measurements, which also visualized whether the disk–osteophyte complexes and calcified ridges were removed completely (Figure 2).

Table 1. Demographics Information of Patients'

Patients	Age	Gender	Level of disc Hernia	Osteoporosis	Systemic diseases
1	40	Male	C4-5, C5-6, C6-7	No	No
2	47	Male	C4-5, C5-6, C6-7	No	No
3	58	Male	C3-4, C4-5, C5-6, C6-7	No	No
4	62	Male	C3-4, C4-5, C5-6, C6-7	No	No
5	51	Male	C4-5, C5-6, C6-7	No	No
6	44	Female	C4-5, C5-6, C6-7	No	No
7	50	Male	C4-5, C5-6, C6-7	No	No

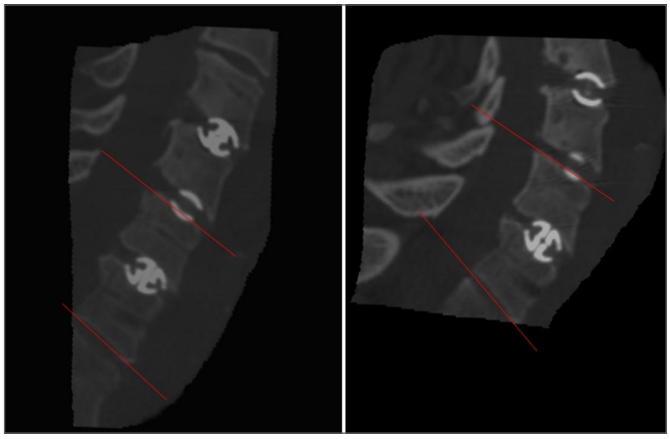

Figure 2. Sagittal 80° range of motion (ROM) of the functional spinal unit, which was defined as the angle formed by lines drawn at the superior margin of the upper vertebral body and the inferior margin of the lower body on fine spiral CT section of flexion and extension in the median sagittal plane.

Moreover, possible micro-motions at the bone–implant interface must be evaluated before drawing a conclusion. Thus, implant motion was also assessed simultaneously on the same CT sections at each level (Figure 3). For the motion of vertebral endplates, the Cobb method was used on flexion–extension CT images. As the landmark for prosthesis motion, the edge of the prosthesis was used. A digital anglometer was used and confirmed with a pencil perpendicular protractor. With a known intraobserver measurement accuracy of approximately +/−2°, to be 95% certain that an implanted prosthesis has any sagittal motion, an ROM of at least 4° must have

been observed. Movement at the bone–implant interface was documented by digitally subtracting the prosthesis ROM from the vertebral ROM.

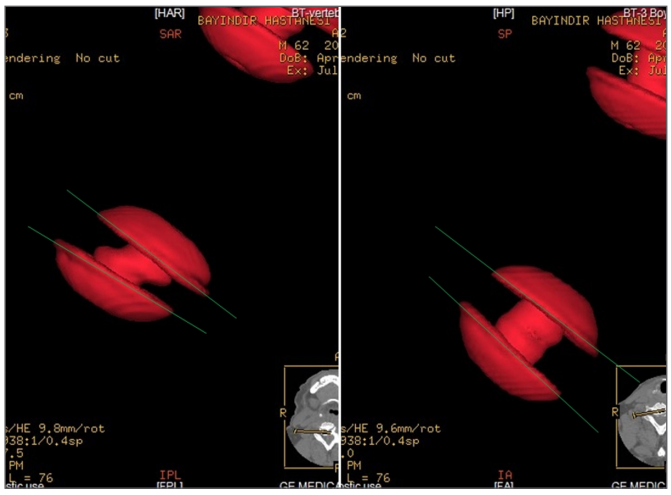

Figure 3. Sagittal 140° range of motion (ROM) of the prosthesis at the same level, which was defined as the angle formed by lines drawn at the edges of the prosthesis on the fine spiral CT section subtracted with the flexion and extension.

RESULTS

The study included patients aged 40–62 years, who had no osteoporosis and previous cervical disc surgery. Surgery was performed on a total of six patients (one female and five male), and 1 year later, six multilevel spondylotic cases were analyzed. Two and four patients underwent two- and three-level surgery, respectively. Some motions could be observed in all patients: in one level, significant (6°) segmental motions at the bone–implant interface could be documented (Figure 4). No adjacent-segment disease was observed in any patient at 1-year follow-up. No residual calcification or postoperative heterotopic calcification was found. No additional findings of radicular or central pathology secondary to a postoperative complication were noted. Cervical palpation revealed non-restricted neck ROM.

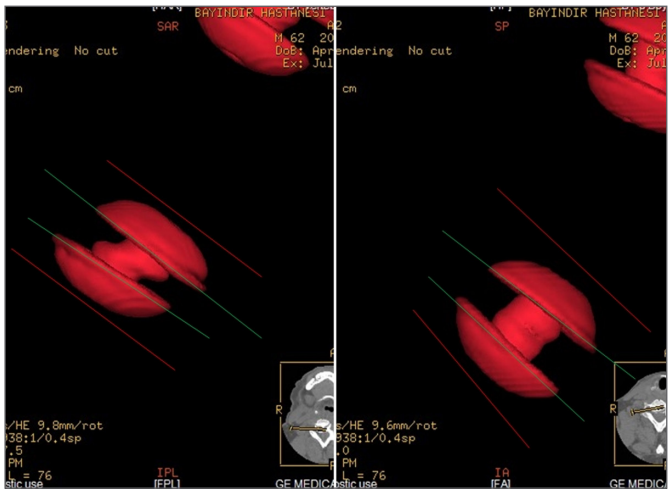

Figure 4. The 6° micromotion at the bone–implant interface was evaluated simultaneously on the same flexion and extension CT sections at the same level by digitally subtracting the prosthesis ROM from the vertebral ROM.

All patients had at least 2° of motion. Thanks to the preoperative endplate curettage and ideal placement of the prosthesis in the vertebra, no postoperative pathology related to prosthesis mobilization was observed in any patient.

DISCUSSION

Cervical disc prosthesis/cages are intended to maintain movements of the intervertebral space and theoretically slow down the degeneration of the adjacent space, allowing the restoration of the physiological curvatures and ROM of the cervical vertebrae to the greatest extent possible. Intermediate follow-up studies in which prosthesis ROMs were measured using dynamic plain X-ray images have shown that by cervical disc prostheses, movements are preserved over time at index levels, and most of the adjacent segments are mobile.[3-6]

This case series was exceedingly limited and heterogeneous, only evaluated six patients, and other more important attributes such as clinical outcomes and long-term durability with osseo-integration of the implant are still being evaluated; therefore, it was not possible to draw any statistically significant conclusions. Furthermore, it dealt specifically with a specific implant design that has a poor overall surface area and at high risk for subsidence, which is not generalizable to other implants that have specific design characteristics with regard to their articulation with the patient's host bone.

Surgical techniques have always been questioned since anterior cervical discectomy was performed. When simple discectomy is performed, the theory that the neural foramen narrows because of the closure of the intervertebral space and the root is compressed has been accepted.[13,14,18,19] Therefore, the excised pathological disc space should be filled with an implant. Since the mobility of the intervertebral discs was limited, fixing the distance to be excised with a material that would create interbody fusion was deemed appropriate, and different implants were placed here.[13] Adjacent-segment disease is one of the most important problems in the follow-up of interbody fusion, and the effectiveness of this method has also been questioned.[10]

Recently, the use of cervical prostheses has become widespread, and implants with different properties have been developed. Prostheses are widely used in cervical intervertebral pathologies, were thought to preserve mobility, albeit partially, and may be a remedy for the development of adjacent-segment disease.[10-14,17] Experimental studies have evaluated the motion efficacy of cervical prostheses; however, studies on patients proving motion efficacy in the late period are not enough.[14] This study aimed to address this scientific need.

The case series is extremely limited and heterogeneous, only six patients were evaluated, the clinical outcomes and other more important features such as osseo-integration, and long-term implant durability are still being evaluated. Therefore, drawing any statistically significant conclusions based on the present findings is not yet possible. We believe that this dynamic CT assessment method is possible at the 1-year postoperative follow-up to determine whether micro-motions occur at the bone–implant interface of this unique cervical arthroplasty device.

A study showed that cervical prostheses undergo heterotopic calcification in the long-term and lose-mobility in the late term.[13] The rate of heterotopic calcification is not very high, and the use of cervical prosthesis in most patients ensures the continuation of vertebral dynamics.[14] Although this study analyzed data from six patients in the early period, the desired dynamic movements continued to an acceptable extent. The findings are valuable in terms of the early maintenance of vertebral dynamics and the absence of adjacent-segment disease caused by immobility in the early period.

CONCLUSION

Given the presented findings, this study provides some preliminary evidence that the above-stated goal can be achieved to provide insight into the motions of surgically treated cervical spine segments under physiologic loads and the more important micro-motions at the bone–implant interface.

ETHICAL DECLARATIONS

Ethics Committee Approval: The study was carried out with the permission of Alanya Alaaddin Keykubat University Faculty of Medicine Clinical Researches Ethics Committee (Date: 02/03/2022, Decision No: 03-07).

Informed Consent: All patients signed and free and informed consent form.

Referee Evaluation Process: Externally peer-reviewed.

Conflict of Interest Statement: The authors have no conflicts of interest to declare.

Financial Disclosure: The authors declared that this study has received no financial support.

Author Contributions: All of the authors declare that they have all participated in the design, execution, and analysis of the paper, and that they have approved the final version.

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