333/ Acta Chir Orthop Traumatol Cech. 87, 2020, No. 5
p. 333–339

ORIGINAL PAPER
PŮVODNÍ PRÁCE

Clinical and Radiological Review of a Semi-Constrained Cervical Disc Replacement with a Ceramic-Ceramic Articulation with a Minimum Seven Years Follow-Up

Klinický a radiologický přehled minimálně sedmiletých výsledků polostištěné náhrady krčního disku s artikulací keramika-keramika

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ABSTRACT

PURPOSE OF THE STUDY

Artificial cervical disc replacement (CDR) has emerged as a viable treatment alternative to fusion for the management of symptomatic compressive radiculopathy and potentially for cervical myelopathy. The aim of our study was to evaluate the clinical and radiological outcomes of patients treated with a second generation semi-constrained CDR with a ceramic-ceramic articulation.

MATERIAL AND METHODS

A prospective cohort study of all patients undergoing a cervical disc replacement for cervical disc pathology, during the period from April 2007 to April 2011 using a ceramic-ceramic disc replacement comprised the study group. 52 patients were available for final clinical and radiological follow-up. Both, clinical and radiological evaluation were performed at each clinical visit at 6 weeks, 6 months, 12 months, 2 years, 5 years and 7 years.

RESULTS

There were a total of 52 patients, with 44 single level cases and 8 two level cases. The NDI improved significantly ($p < 0.05$) from a mean preoperative score of 56 % to a score of 20% at final follow-up. The mean preoperative mobility at the index level unit was 12.2 ± 4.5°, this decreased to 7.9 ± 3.2° at six weeks, but slightly increased to 12.9 ± 2.9° at final follow-up (gain not significant). Heterotrophic ossification (HO) was noted in 13 (25%) patients.

CONCLUSIONS

Cervical disc replacement with a ceramic-ceramic bearing surface is a viable option in the treatment of variety of cervical pathologies. This ceramic-ceramic interface may eliminate the potential problems of metallosis and poly-wear but further longer-term results should be studied.

Key words: Cervical spine; disc replacement; ceramic articulation; neck disability; heterotrophic ossification.

INTRODUCTION

Traditionally, anterior cervical discectomy and fusion (ACDF) is accepted as the gold standard procedure for symptomatic degenerative cervical disc disease (34). However, adjacent segment degeneration leading to disc dehydration and osteophyte formation can occur due to the biomechanical changes after a fusion surgery (32, 37). Adjacent segment disease after an ACDF is commonly seen, with a large proportion of these patients (7% to 25%) being symptomatic (3, 13, 14, 15). This entity is now popularly coined adjacent segment pathology and is divided into radiological and clinical pathology (17). However, it is still debatable if these changes are attributable to the natural history of spondylosis and aging or due to the biomechanical effects of fusion.

Fusing a cervical spinal segment affects the segmental motion, which can have an untoward biomechanical effect on adjacent discs (12, 21, 29, 38).

In the recent past, artificial cervical disc replacement (CDR) is also used as a treatment modality in the management of symptomatic compressive radiculopathy and myelopathy with good results, especially in the younger active patients (1, 31). Also, a recent study has demonstrated better quality of life outcomes after cervical disc replacement (35).

The first generation artificial cervical disc replacement very much followed the design of the existing large joint arthroplasty devices (e.g.: ball and socket systems) to provide a certain degree of motion at the replaced seg-

ments (2, 11, 24, 25). However, unlike large joints, we now understand that movement at the intervertebral disc joint is very complex and differs from those of the large joints. It involves coupled motions requiring at least 6 degrees of freedom (4, 28). For ADR to be effective, it should mimic the natural spinal kinematics as closely as possible while restoring motion and maintaining the sagittal alignment of both the treated level and the whole cervical spine (33). Both in-vitro (28) and in-vivo (26) studies have demonstrated restoration of physiological and coupled motion after CDR. It should also be durable and biocompatible. Insertion of the prosthesis should be safe and more importantly, the clinical success should be at least equivalent to a fusion (30).

There is an increasing enthusiasm about motion preserving surgery for cervical disc pathologies. But, an understanding of the long-term outcomes and risks associated with these devices is important, especially in the wake of significant and catastrophic results with some of the large joint replacements (e.g.: metallosis and wear debris). Cases of delayed hyper-reactivity to metal ions after cervical disc arthroplasty, and polyethylene wear and tear have been reported and are a concern (6, 10, 16, 18). Newer generation of ceramic-ceramic bearing disc replacements comes with the potential to offset these complications and provide excellent biocompatibility, lower wear rates, and fewer toxic wear particles which may reduce osteolysis of bone, as seen in total hip arthroplasty (27). MRI compatibility of the prosthesis is important for post-operative assessment.

The purpose of this study was to study the clinical and radiological outcomes of patients treated with a second-generation semi-constrained cervical disc replacement (CDR) with a ceramic-ceramic articulation.

MATERIAL AND METHODS

We conducted a prospective cohort study of all patients undergoing a cervical disc replacement during the period from April 2007 to April 2011 using the Discocerv (Scient'x - Alphatec Spine Quality Management System). This implant is indicated in patients with degenerative disorders of the cervical spine, without instability in a tertiary level teaching hospital. 55 patients underwent cervical disc replacement using the Discocerv prosthesis.

The study was registered with the clinical audits department at the institute and approval obtained.

The inclusion criteria were: degenerative cervical disc disease, disc herniation with neck and radicular pain with or without neurological deficit and / or myelopathy. All patients had failure of initial conservative treatment. All patients had an MRI scan proven diagnosis with corresponding clinical correlation. In some cases, a CT scan was done to confirm absence of advanced degenerative changes in the segment(s). Exclusion criteria included patients with instability, infection and tumour and patients with hybrid constructs (CDR plus ACDF).

The two senior authors performed all surgeries. The operative technique and post-operative regime were standardized for all patients. All patients were followed up at 6 weeks, 6 months, 12 months, 2 years, 5 years and 7 years. 52 patients were available for final clinical and radiological follow-up and hence included in the study. Further demographic data to include BMI, ASA grade and medical co-morbidities were recorded.

The prosthesis

This prosthesis is a semi-constraint prosthesis composed of two parts, allowing a spherical motion by "head-cup" coupling. The prosthesis includes a spherical upper convex head formed on the first insert while another spherical concave cup is formed on the lower second insert. This design helps to preserve mobility within physiological ranges, with 18 degrees of range of motion in flexion-extension and lateral bending.

It is manufactured from ELI titanium and inserts are made of ceramic material (Zirconia and Alumina) providing optimal wear properties. The shape of the device, convex upwards in the sagittal plane and downwards in the frontal plane, is designed to fit exactly the disc space. Given its titanium and ceramic composition, the prosthesis is MRI compatible if needed.

Surgical technique

All patients had a standard anterior approach to the cervical discs. Standard thorough discectomy using a microscope was carried out. Meticulous preparation of the endplates with a large curette was undertaken with care not to damage the endplate. The prosthesis design facilitates the insertion without exposing or creating a channel (keel) into the cancellous bone. Trial insertion of the prosthesis was followed by definitive placement of the artificial disc. Antero-posterior and lateral intra-operative imaging was performed for correct centering of the implant.

All patients were admitted to a high dependency unit for 24 hours to monitor the airway and potential neck swelling. This is standard practice for all anterior cervical spine surgery in our unit.

Clinical evaluation

Pre and post-operative clinical evaluation was performed using the validated Visual analogue scale (VAS) and the Neck Disability Questionnaire (NDI). All evaluation was performed at each clinical visit at 6 weeks, 6 months, 12 months, 2 years, 5 years and 7 years. All the PROMS evaluation were done by specialist spinal physiotherapy practitioners independent of this study.

All patients have further follow-up appointments to carry out clinical and radiological evaluation every two years or earlier if need arises.

Radiological evaluation

All patients had a standardized antero-posterior (AP) and lateral radiograph in neutral position. Further lateral radiographs in maximum flexion and extension were performed (Figs. 2, 3, 4, 5 & 6).

In order to perform a qualitative evaluation of the disc replaced and the adjacent segment evolution, all changes

in the disc such as disc narrowing, presence of osteophytes or vertebral endplate sclerosis were recorded. Also, the migration of the device was assessed, if any from the lateral radiographs in neutral position.

Further radiographic evaluation was performed on both pre and post-operative X-rays with measurement of the regional and local lordosis on static radiographs and range of flexion-extension mobility on dynamic radiographs.

Flexion-extension mobility was measured for both index level and the adjacent levels. Ossification or evidence of fusion in the replaced segment and adjacent segments were noted. The occurrence of heterotrophic ossification (HO) was interpreted on lateral radiographs using the Mehren/Suchomel modification of the McAfee classification (22) used for lumbar spine:

Grade 1– segments with new HO formation not reaching the intervertebral space;

Grade II – HO reaches the intervertebral space but segmental movement is not limited;

Grade III – important bridging ossifications with limited, but possible movement;

Grade IV – segmental fusion.

All radiographs in our institute are digitalized using the picture archiving and communication system (PACS) imaging technology**.** Two independent observers not part of this study performed all radiological measurements.

Statistical analysis

To analyze any demographic parameters and basic characteristic differences in age, BMI and pre and post-operative values of all quantitative parameters like ROM, NDI and VAS, the Student's t-test and Wilcoxon tests were employed.

The segmental motion pre and post-operatively was additionally calculated using a vector odd X, Y and Z-axis. A p value < 0.05 was seen as statistically significant.

RESULTS

Patient characteristics

52 out of the 55 patients who had the prosthesis implanted and had a minimum follow up of 7 years were evaluated clinically and radiologically. 3 patients (5.4%) were lost for follow-up. The preoperative clinical diagnosis was herniated cervical disc in 39 patients and cervical canal stenosis in 13 patients. An associated cervical myelopathy was noted on the MRI scan in 7 patients with associated early clinical signs. There were 44 single level cases and 8 two level cases totalling 60 levels treated. The following levels were treated: C4-C5: 2 patients (3%); C5-C6: 36 patients (60%) and C6-C7: 22 patients (37%). No patients died in the follow-up period. 36 of these patients were males and C5-6 was the commonest level of surgery. The mean age at operation was 44 years (23 to 59 years). Cervical disc herniation with corresponding radiculopathy and neurology was the commonest diagnosis. The statistical summary results for the background characteristics of this study group are provided in Table 1.

Table 1. Patient baseline characteristics

Patient baseline characteristics	Value [N=52]
Age	range: 23 to 59 years mean = 44 years
Males: N [%]	36 [69%]
Number of treated levels, N=60	one level = 44 two levels = 8
Implant levels; N [%]	C4-5 = 2 [3%] C5-6 = 36 [60%] C6-7 = 22 [37%]
Smokers: N [%]	22 [44%]

Surgery

The average duration of the surgery was 141 minutes (range: 70 to 240 minutes). No intra-operative complications were recorded. One patient had post-operative headache and right facial numbness, which was unexplained and resolved without intervention in five days. Other complications of cervical arthroplasty, such as device migration, infection or neurological damage, did not occur in our study. All patients had good functional movements in their neck at the time of discharge. The mean length of stay (LOS) stay was two days (range from one to six days).

Clinical outcome

At 6 months post-operative follow-up, all patients had significant recovery from their preoperative motor and sensory loss. The VAS score for neck pain decreased from a mean preoperative score of 6.1 to 3.1 at 1 year, which was significant according to the paired sample t-test. The NDI improved significantly ($p < 0.05$) from a mean preoperative score of 56% to a score of 20% at final follow-up (Fig. 1).

Radiological analysis (Figs. 2–6)

The mean preoperative mobility of the cervical spine as a whole was 49.8 ± 11.7° (mean ± standard deviation). Postoperatively, the range of motion decreased to 32.4 ± 9.8° at one month, but slightly increased to 53.1 ± 15.6° after one year but this increase was not statistically significant. The mean preoperative mobility at the index

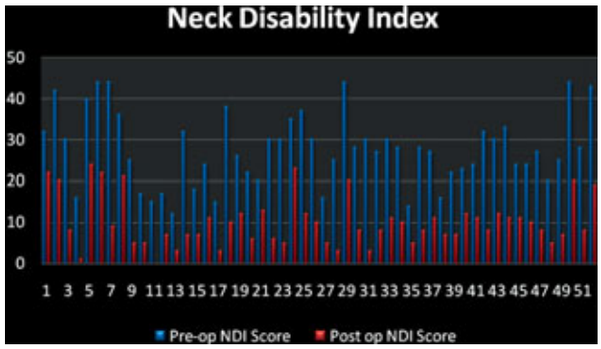
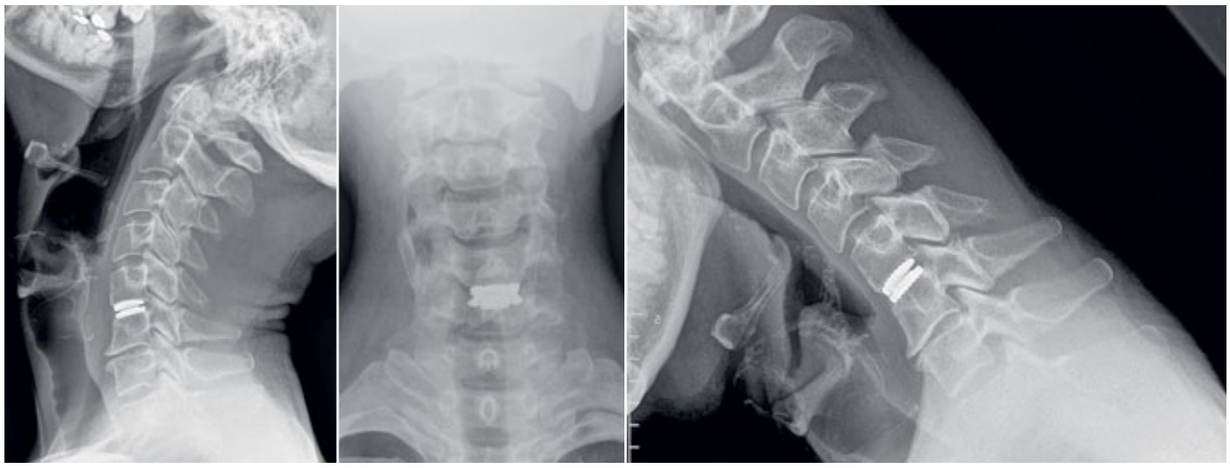


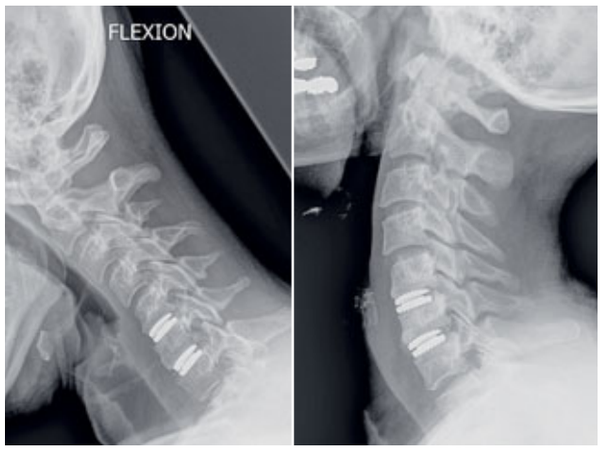
Fig. 1. NDI score.



Figs. 2, 3, 4. Extension, AP and flexion X-rays of 38 y male (at surgery) 10 years follow up, extension C5-C6 is 0, flexion is 6.2 deg.

level unit was 12.2 ± 4.5°, this decreased to 7.9 ± 3.2° at six weeks, but slightly increased to 12.9 ± 2.9° at 1 year (gain not significant). In other words, the treated segment preserved or improved its preoperative mobility. The mean neutral preoperative angle from C2-C7 of the cervical spine as a whole was -13.5 ± 10.2° and thus was lordotic. At final follow-up it improved to -11.0 ± 4.9°, but the initial lordosis was not completely recovered. Again, the difference was not statistically significant. Subsidence of the prosthesis of less than 2mm was observed in three patients at the ventral part of the lower end plate. This did not have any clinical impact.

Heterotrophic ossification (HO) was noted in 13 (25%) patients. Grade 1=1 (1.9%); grade 2=1 (1.9%); grade 3=7 (13.5%) and grade 4=4 (7.7%). The presence of HO did not affect motion of the cervical spine as a whole. In our study, HO seems to coincide with pre-existing minor spondylosis.



Figs. 5 and 6. Flexion and extension X-rays of 45-year-old female, 7 years follow up, flexion shows 0 degrees of lordosis, extension 15 degrees of lordosis.

DISCUSSION

The primary aim of our study was to validate the safety and stability of this novel ceramic-ceramic cervical disc replacement.

Cervical spondylosis is a common pathological condition that affects the adult spine, and is the most frequent cause of cervical radiculopathy and myelopathy in older patients. Anterior cervical discectomy and fusion is regarded as a gold standard treatment and is reported to have high success rates (34, 37). However, fusion of the cervical spine can have biomechanical consequences. Loss of mobility at one functional spinal unit can direct the load to adjacent level mobile segments (13, 32). This can result in adjacent segment pathology (3, 13, 14, 15). However, the frequency, cause, and clinical significance of these adjacent segment changes remain controversial. Different rates of adjacent segment degeneration have been reported in the literature and have varied according to the definition of adjacent segment degeneration and possibly the age of the patient and their activity levels.

In recent years, Hilibrand et al. (13) classified degeneration of adjacent segments into ‘‘adjacent segment degeneration’’ and ‘‘adjacent segment disease’’. More recently Riew et al. proposed a simple, descriptive terminology: Adjacent segment pathology

(ASP), which includes all the changes that occur adjacent to a previously operated level. Under the umbrella of this heading, further terminologies are described: “Radiographic Adjacent Segment Pathology” (RASP) which refers to radiographic changes at the adjacent segment and “Clinical Adjacent Segment Pathology” (CASP) which refers to clinical symptoms and signs that occur at the adjacent segment. This is almost always associated with RASP (31).

A meta-analysis by Yin et al. (39) conducted by a comprehensive search in MEDLINE(®), EMBASE, and Cochrane Central Register of Controlled Trials of 503 papers concluded that in the treatment of symptomatic cervical disc pathology, a cervical disc arthroplasty appears to provide better function, a lower incidence of reoperation related to index surgery at 1 to 5 years, and lower major complication rates compared with fusion. However, cervical disc arthroplasty did not reduce the reoperation rate attributable to adjacent segment degen-

eration than fusion. Further, it is unclear whether these differences in subsequent surgery including arthroplasty revisions will persist beyond 5 years. Hence, reporting of longer-term follow-ups are important.

The primary aim of the spinal arthroplasty is to preserve motion. But, spinal arthroplasty has a relatively short history in comparison to other joint replacements. Most of the first-generation artificial cervical discs fail to fully replicate the normal visco-elastic disc structure, lacking internal elastic stiffness or restraint and axial compressibility (30, 33). The newer generation artificial cervical disc represents advancement in tribology. There is an analogy to the history of other large joint replacements and advancements in the bearing surface and biomaterial technologies including the manufacturing of cross-linked polyethylene and ceramics. Also, lessons learnt from complications associated with wear particles with earlier biomaterials and bearing surfaces have paved way for better disc replacements (27).

Cervical discs do not follow a pure uniplanar motion. Also, movement into any range is not the simple sum of equal motion from one vertebra to the next. General flexion and extension motion of the neck does not necessarily reflect the movement among vertebrae in the cervical spine. In fact, a vertebra may experience its greatest range of motion in flexion or extension before the cervical column itself has fully flexed or extended. An in vitro biomechanical study of C4-C5 intervertebral disc replacement using a cadaveric model to investigate the degree of motion afforded by a ball-and-socket cervical intervertebral disc prosthesis design demonstrate that a ball-and-socket design can replicate physiologic motion at the affected and adjacent levels. More importantly, the data indicate that motion coupling, which is most dramatic in the cervical spine and plays an important biomechanical role, is maintained (28).

Pickett et al. (26) conducted an in-vivo kinematic analysis of the cervical spine following implantation of an artificial cervical disc. In this study, motion was preserved in the operated spinal segments (mean range of motion 7.8 degrees) up to 24 months following surgery. Overall cervical motion (C2-C7) was moderately but significantly increased during late follow-up. Sagittal rotation, anterior and posterior disc height, translation, and center of rotation coordinates did not change significantly following surgery. They concluded that the Bryan artificial cervical disc provided in vivo functional spinal motion at the operated level, reproducing the preoperative kinematics of the spondylotic disc. In our own study, the cervical motion improved slightly at one- year follow-up both at the index level and the whole cervical spine.

Cervical disc arthroplasty may offer benefits over arthrodesis as discussed before, however new potential complications can be encountered. One of the most studied complications of cervical total disc replacement is the formation of heterotrophic ossification (HO) (23). The etiology of HO associated with cervical disc replacement is not established. Repeated trauma to the longus colli musclulature is implicated in some studies while other authors have implicated extensive vertebral endplate preparation or milling of the bone as a possible factor leading to HO formation. Clearly, if HO reaches the point of spontaneous fusion in a large number of patients, the theoretical benefit of motion preservation is lost. An example of this was found in study by Leung *et al*.(19), wherein 62% of patients had less than 2 degrees of motion at the affected surgical levels. In order to reduce the incidence of HO, the protocol of the Bryan FDA IDE study required that patients receive a 2-week postoperative course of a nonsteroidal anti-inflammatory drug (surgeon's choice). A more recent meta-analysis of cervical disc replacements (CDR) showed a 44% prevalence of HO at 12 months and this rose to 58% at 24 months (7). In our study, we assessed the development of HO using the modified Mehren classification. In our study, we encountered 13 cases of HO with 4 patients having grade 4 ossification (i.e minimal mobility). Several other studies have reported a high incidence of HO (5, 20, 36). However, it was noted that patient selection and/or the operative technique might have contributed to the high prevalence of osteophyte formation. We have adapted our practice to include a CT scan for all patients with suspected osteophytes. We also pay much more attention to sealing any exposed cancellous bone surface created by osteophyte resection with bone wax. Also, because the prosthesis design does not require endplate violation which helps to minimise HO formation. HO progression was also noted to be related to the time elapsed post-operatively and grade 3 and 4 HO may lead to spontaneous fusion and must be anticipated in long-term follow-up studies. However, the occurrence of HO did not affect the clinical outcome and mobility in these studies, an experience we share in our own study.

There are also general concerns related to the use of disc arthroplasty with regard to material wear creating debris and the resultant immunological response. Goffin et al. (9) noted that motion at the articulation can generate wear debris. This can further incite an inflammatory reaction leading osteolysis, and/or loosening with resultant pain. Cavanaugh et al. (6) reported one case involving a delayed hypersensitivity reaction to metal ions after cervical arthroplasty (TDR); surgical exploration of the disc space revealed chronic inflammatory debris, and abnormal cartilaginous tissue. Guyer et al. (10) described 4 patients (3 lumbar disc replacements, and 1 cervical TDR) who had undergone metal-on-metal disc replacements and sustained delayed reactions attributed to wear debris; although the subjects initially had good surgical outcomes, within a few months they developed axial pain and/or radicular symptoms. Imaging studies after cervical disc replacement revealed a mass lesion attributed to metal ion debris in all cases. The patient with cervical spine involvement had grey-tinged tissue observed during a second operative procedure (revision surgery) that suggested metallosis; pathology confirmed a lymphocytic reaction attributed to the implant. Nevertheless, it remains unclear as to whether these devices fail from pre-existing metal hypersensitivity, or whether the patient becomes hypersensitive to the implanted metal. However, catastrophic results with metal on metal

bearing surface in hip joint arthroplasty is well documented in recent times leading to accelerated failure.

Fan H et al. (8) have reported a rare case of Bryan disc implantation failure due to a broken polyurethane sheath. There was reported bone in-growth at implant-bone interface and wear debris leaking from the ruptured sheath. In another prospective retrieval analysis of a Prodisc-C cervical disc replacements, Lebl DR et al. (18) demonstrated impingement of the metal endplates and third body wear. Long-term studies to determine the clinical impact of these wear patterns need to be performed.

As the principles of joint arthroplasty become increasingly refined and more widely established, new designs are being developed that require careful evaluation for their propensity to generate wear debris in vivo. In the past several years, new designs intended to improve clinical performance have emerged in both total hip replacement and total spinal disc replacement. Advances in these types of implants have the potential for major clinical impact in the coming decade, due to the large number of patients seeking treatment of large joint arthritis as well as back pain, neck pain, and radiculopathy.

Learning from the advancements in total hip replacements and the available literature on biomaterials and tribology including concerns with metal-on-metal articulations, a viable option with ceramic-ceramic articulation seem to offer a favorable alternative for cervical disc replacements. But the overall success will depend on the demonstration of long-term clinical efficacy, with regards to both clinical outcomes and cost-effectiveness. To date, our understanding of the optimal device design and biomechanics remain under investigation.

The strength of this study is the homogenous population group, standardized surgical and follow-up methodology by the two senior authors, independent clinical and radiological review, high follow-up rates and the limited available literature on ceramic-ceramic cervical disc replacements.

The limitations of this study include the small numbers of patients and the absence of a control group. Long-term studies with more patient numbers are required to assess the effect of the prosthesis in relation to adjacent segments and need for further surgery.

CONCLUSIONS

Based on our minimum seven-year follow-up study of cervical disc replacement with a ceramic-ceramic bearing surface, this appears to be a viable option in the treatment of variety of cervical pathologies although the indications are narrower than initial proposals. It seems the ideal indication is in younger patients with well mobile discs and soft disc herniations. The ceramic-ceramic interface may eliminate potential problems with polyurethane rupture, metallosis and polyethylene wear. All patients had satisfactory clinical and radiological outcomes. These patients should be rigorously followed, both clinically and radiologically and further long-term results should be reported.

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