Cervical Total Disc Replacement: Biomechanics

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Abstract

Cervical disc arthroplasty is an evolving surgical concept designed to treat certain pathological conditions of the cervical spine. The introduction of arthroplasty devices has stimulated novel studies aimed at understanding motion in the cervical spine and has also driven investigators to examine the consequences that result from surgical alteration of pathological structures. The study of cervical "biomechanics" and "kinematics" has evolved from basic analysis of flexion/extension radiographs to complex, computer-assisted modeling that aides investigators in understanding concepts such as center of rotation (COR), functional spinal unit (FSU)

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translation, and coupled motion. In recent years kinematic studies have contributed to our understanding of adjacent level degeneration and index-level facet loading. We review the young science of cervical arthroplasty biomechanics.

Keywords

Cervical spine · Arthroplasty · Biomechanics · Kinematics · Finite Element · Motion

Introduction

The design of arthroplasty devices for the human cervical disc has brought about a renewed interest in the biomechanics of the cervical spine. Modern techniques of assessment and measurement are currently being employed parallel to traditional outcome measurements in the hope that such information may advance the collective understanding of disc arthroplasty on cervical motion.

Concepts of cervical arthroplasty have undergone a dramatic evolution since the development of the original Bristol/Cummins disc arthroplasty device. At a basic level, motion retention/preservation is a primary kinematic measure of device success in this procedure, though the current indications for the procedure are typically of neurological origin. Retention of motion or "motion sparing" in cervical arthroplasty has quickly evolved in device design over the past 20–30 years. Materials used in disc arthroplasty have also changed. The evolution of metal-on-metal implants has occurred in parallel with the development of novel bearing concepts incorporating metal alloys, polyethylene, and ceramics.

Currently the term "cervical arthroplasty" is applied to the procedure of "disc arthroplasty" or "disc replacement." A number of these devices are in the process of early use or are involved in US Food and Drug Administration (FDA) trials. While the early data from clinical trials is encouraging, there remains a need to demonstrate the biomechanical properties of these devices and techniques in the intermediate and long term. Cervical arthroplasty of the disc alone is not intended to address the posterior elements at the index surgical level – leaving open the option for future modifications of the concept of cervical arthroplasty and kinematic motion sparing.

Background

The cervical spine consists of vertebral bodies with intervening discs and soft tissue structures that support motion and protect the neural and vascular elements. From a biomechanical perspective, these discs and their corresponding facets function in load bearing and motion transfer allowing for flexion/extension, lateral bending, and rotation as well as complex coupled motions. In addition to its biomechanical functions in motion, the cervical spine serves as the protective passage for the spinal cord and vertebral arteries.

Cervical spondylosis is the process by which the cervical spine most frequently loses motion and is occasionally to blame for ensuing neurological phenomena which have been the traditional indication for surgical interventions. Disc degeneration is well documented as the transition from mild degenerative disc disease to multilevel cervical spondylosis progresses. For many years, the surgical treatment for pathology in the cervical intervertebral disc has been limited to procedures which remove pathologic disc material and address the bony and neurologic pathology in the region of the excised disc.

Anterior cervical discectomy and fusion (ACDF) is a proven intervention for patients with radiculopathy and myelopathy (Bohlman et al. 1993). It has served as the standard by which other cervical and spinal disorders may be judged as the result of its high rate of success. The success of this technique is often judged based upon its consistent ability to relieve symptoms related to neurological dysfunction. In this sense, the clinical results with regard to the patient's index complaint are outstanding. The radiographic results of this technique are also initially predictable with a high rate of fusion. Plating techniques have diminished the need for postoperative immobilization or eliminated them entirely (Campbell et al. 2009). However,

because of limitations specific to this procedure, investigators have developed surgical alternatives to fusion that attempt to address the kinematic and biomechanical issues inherent in it.

A major concern related to the treatment of cervical degenerative disc disease (DDD) and spondylosis with ACDF are the issues of adjacent segment degeneration and adjacent segment disease (ASD). Adjacent segment degeneration is manifest as the radiographic appearance of degenerative change at a level directly above or below a level treated with a surgical intervention – typically being associated with degeneration of a level adjacent to a fused level. Adjacent segment disease (ASD) is defined as adjacent segment degeneration causative of clinical symptoms (pain and/or neurological disorders) severe enough to lead to patient complaint and/or require operative intervention (Hilibrand et al. 1999). Adjacent segment degenerative change has been reported to be as high as 92% by Goffin et al. who wrote a long-term follow-up on patients after treatment with anterior interbody fusion (2004). While there remains some debate as to the causation of adjacent segment degeneration – with a mix of postsurgical (altered biomechanics) and naturally determined aging (genetics) cited as root causes – there is little debate as to the existence of this phenomenon. A number of studies have made a consistent point of distinguishing between radiographic "degeneration" and symptomatic "disease" (Goffin et al. 2004; Robertson et al. 2005).

There is clinical evidence to support the postsurgical nature of ASD with respect to kinematics. In patients previously treated with fusion, adjacent segment disease has been documented at a rate of 2.9% of patients per annum by Hilibrand et al., and 25% of patients undergoing cervical fusion will have new onset of symptoms within 10 years of that fusion (Hilibrand et al. 1999). This study has received a great deal of attention and has led to further investigations as to kinematic and biomechanical causation. Other reports have focused on the recurrence of neurological symptoms and degenerative changes adjacent to fused cervical levels (Goffin et al. 1995, 2004). The concept that adjacent levels need to kinematically compensate for loss of motion in the fused segment may also be valid. Segments adjacent to a fusion have an increased range of motion and increased intradiscal pressures (Eck et al. 2002; Fuller et al. 1998).

Total intervertebral disc replacement (TDR) is intended to preserve motion, minimize limitations of fusion, and may allow patients to quickly return to routine activities. The primary goals of the procedure in the cervical spine are to restore disc height and segmental motion after removing local pathology that is deemed to be the source of a patient's index complaint. A secondary intention is the preservation of normal kinematics at adjacent cervical levels, which may be theorized to prevent later adjacent level degeneration. Cervical TDR avoids the morbidity of bone graft harvest (Silber et al. 2003; St. John et al. 2003). It also may avoid complications such as pseudarthrosis, issues caused by anterior cervical plating, and cervical immobilization side effects.

General Cervical Spine Biomechanics

Motion in the cervical spine implies a direct interaction between two or more cervical vertebrae and their supporting structures. A motion segment of the cervical spine, often analyzed as a functional spinal unit (FSU), is complex. The cervical spine is much more than a single FSU, and investigators have found that much more complex kinematic relationships exist as they seek to understand not only the effects of various treatments on a single ("index") FSU but also the effects of that same treatment on adjacent or remote FSUs.

Each FSU consists of three compartments (the disc and two facets) and multiple supporting ligamentous and soft tissue structures. The normal cervical spine exhibits complex coupled motions in addition to the traditionally understood independent kinematic motions such as anterior-posterior translation during flexion and extension. An implant designed to replace the cervical disc should consider the effect of all three compartments and the multiple ligamentous and soft tissue structures present in this complex environment.

One of the primary goals of cervical disc replacement is to reproduce "normal kinematics" after implantation. Fortunately, numerous kinematic studies of various designs have been undertaken parallel to US FDA (IDE) studies. Collectively, these studies may be classified by device and/or study design criteria. Some investigators have taken advantage of novel finite element (FE)-based techniques, while others have used more traditional in vivo or in vitro means. Review of these studies is instructive in understanding the current state of kinematic knowledge with regard to cervical TDR. Over time, similar studies may suggest which type of implant design will provide "kinematically accurate" motion.

Early device designs made use of ball-in-socket articulations within the device. A ball-in-socket (constrained design) does not allow for natural translation. The complexity of the cervical spine requires a "balance" of all the significant structures including facets and ligaments. A ball-in-socket, by its design, dictates the kinematics of motion irrespective of traditional FSU behaviors and eliminates the normal anterior/posterior translation that the facets provide. A number of studies describe the increased forces born by these facets – a phenomenon sometimes described as "kinematic conflict."

The most significant effect of this change in facet loading is in extension. During flexion the facets "un-shingle" and reduce their involvement in constraining the motion of the functional spine unit. However, when the spine goes into extension, the facets "shingle" and become more involved in constraining the motion. Thus, with a constrained facet joint and a constrained arthroplasty device, one would expect to see binding or limited motion as one joint works against the other in the FSU. For this reason device designers have introduced less constraint in more recently designed devices.

There are a number of methods by which kinematic data may be derived. In vivo measurements in the human are often made through review of flexion and extension radiographs that are digitized and subsequently measured with software packages (Sasso and Best 2008) (Figs. 1 and 2). Alternatively, nonhuman in vivo measurements may occur in translational projects wherein the spine is tested via histological and radiographic means as well as benchtop environments with mechanical loading devices, optical tracking (Fig. 3), and pressure sensors. In vitro testing of human cadaveric specimens occurs via similar benchtop testing protocols with the obvious exclusion of histological means (Figs. 3 and 4).

Computer-assisted finite element (FE) modeling is a technique by which a computer-generated

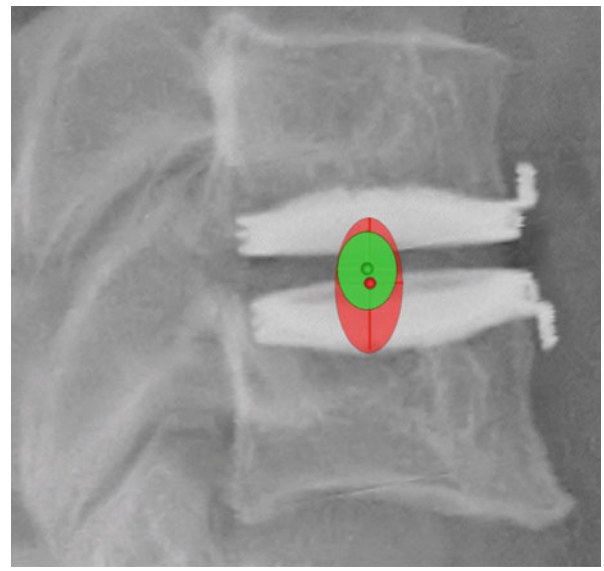

Fig. 1 The BRYAN® Cervical Disc Prosthesis is demonstrated in vivo in this lateral cervical radiograph. The center of rotation (COR) has been calculated pre- and post-placement of the arthroplasty prosthesis at the index surgical level. Software allows for in vivo analysis of kinematic changes in humans via radiographic means over time. Changes in COR may correlate to long-term kinematic outcomes, device survival, and adjacent level changes. (© Courtesy of Rick Sasso, Indianapolis, IN)

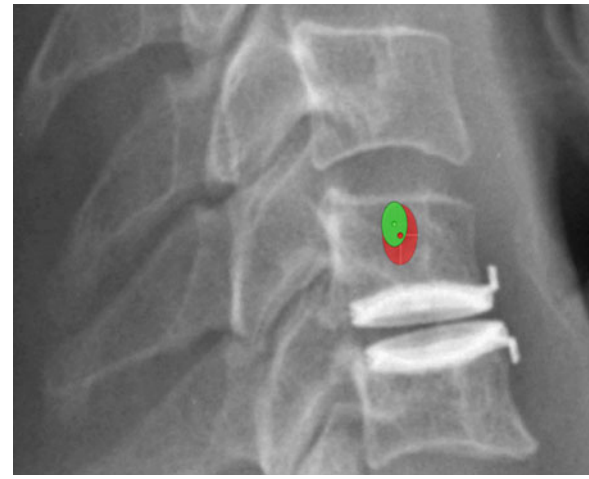

Fig. 2 The BRYAN® Cervical Disc Prosthesis is demonstrated in vivo in this lateral cervical radiograph. The center of rotation (COR) has been calculated pre- and post-placement of the arthroplasty prosthesis at the adjacent surgical level. (© Courtesy of Rick Sasso, Indianapolis, IN)

Fig. 3 Explanted spinal specimens may be tested in a number of ways. Optical tracking allows for real-time tracking of motion and is commonly used in conjunction with forces applied to the cervical spine in a controlled, monitored environment. Cameras on this OptiTrack™ Device (NaturalPoint® Inc., Corvallis, Oregon) follow the motion of rigid bodies. (© Courtesy Nicole Grosland, PhD and Joseph D. Smucker, MD – The University of Iowa and Indiana Spine Group)

model of the cervical spine is modified to include surgical procedures such as ACDF or arthroplasty techniques and principles (Ahn and DiAngelo 2008; Kallemeyn et al. 2009). Specimen-specific modeling is a more refined method of testing such principles (Kallemeyn et al. 2009) (Fig. 5). FE modeling has the potential advantage of providing investigators with a more flexible testing environment given the assumption of model-specific limitations.

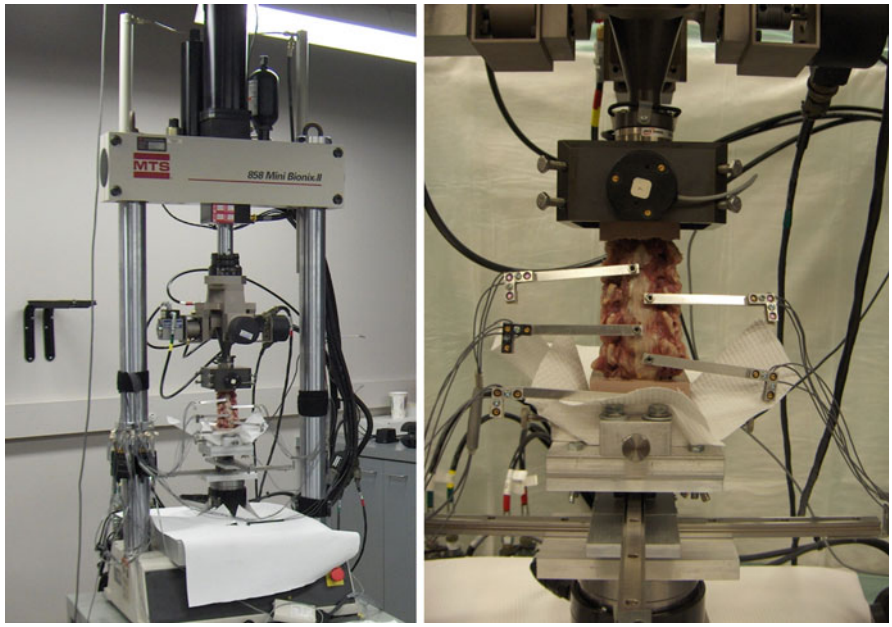

Fig. 4 Controlled application of force within the defined degrees of freedom in the cervical spine is applied to create motion in an ex vivo environment. This MTS™ 858 Mini Bionix II system (MTS Systems Corp., Eden Prairie, MN) applies precise force via computer-controlled hydraulic mechanisms. Optical tracking via the OptiTrack™ system is combined with this controlled application of force to track and analyze simple and coupled motions created in this multi-FSU spinal specimen – allowing for real-time tracking of motion. (© Courtesy Nicole Grosland, PhD and Joseph D. Smucker, MD – The University of Iowa and Indiana Spine Group)

History of Disc Arthroplasty Design Kinematics

An understanding of the evolution of cervical TDR serves as an important lesson in the concepts of kinematic device design properties and articular constraint. In the late 1980s, Cummins et al. (1998) developed a metal-on-metal ball-and-socket cervical disc replacement comprised of 316 L stainless steel. With the acquisition of this technology and the later development of new metal-on-metal devices, a rapid transition evolved to the most recent device, the PRESTIGE® LP (Medtronic Sofamor Danek, Memphis, TN). A predecessor of this device, the PRESTIGE® ST (Medtronic Sofamor Danek, Memphis, TN), is currently approved for human use by the US FDA.

A number of devices have evolved parallel to the metal-on-metal implants and include the BRYAN® Disc (Medtronic Sofamor Danek, Memphis, TN), the Porous Coated Motion Prosthesis (PCM®, NuVasive, San Diego, CA), the SECURE-C® (Globus Medical, Audobon, PA), and the MOBI-C® (Zimmer Biomet, Parsippany, NJ). To date, several such devices have obtained approval for use in the US market: the PRODISC-C® (Centinel Spine, West Chester, PA) and the BRYAN® Disc. Each of the other devices is in the process of limited human trials and/or US FDA-IDE submission and represents an alternative to metal-on-metal bearing surfaces which have the potential for metal debris and systemic concentration of metal ions.

While the ideas of bearing surfaces, wear debris, and constraint are not new to discussions with regard to arthroplasty in general, they are relatively young in the spine. In fact, a full understanding of the term "constraint" with regard to cervical kinematics post-disc arthroplasty has not been agreed upon – as constraint may arise within the device or as a result of the local anatomy

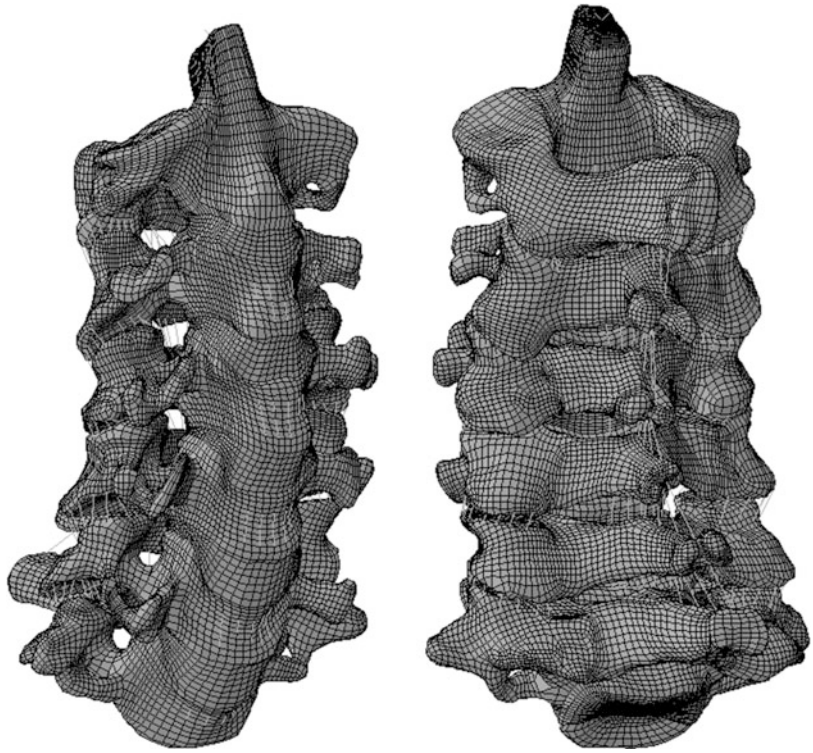

Fig. 5 Dorsal and ventral views of a finite element (FE) model of the human cervical spine (C2-C7) are presented. Multiblock analysis occurs after biomechanical properties are assigned to bony and soft tissue structures. Initial specimen-specific models are created from computed tomograpic (CT) analysis of the human cervical spine. The specimen may then be analyzed in a computer environment with simulation of motion via computer applied forces to the model. The model may be further modified via implantation of spinal devices such as disc arthroplasty devices. Facet forces, intradiscal forces, and other kinematic measurements such as COR may be calculated. (© Courtesy Nicole Grosland, PhD and Joseph D. Smucker, MD – The University of Iowa and Indiana Spine Group)

(facets, PLL, etc.). As the knowledge base in spine TDR increases, intelligent investigations and discussions will include many of these concepts and may redefine our understanding of them.

It is relevant to understand that the load born by devices in the cervical spine is dissimilar to that born in the lumbar spine. The biomechanical environment of the cervical spine has been taken into account in the design of the current generation of these devices. As intermediate- and long-term studies on individual devices become available, the design concepts of these initial devices will have the opportunity for continued examination in their in vivo environment.

Current Kinematic Studies

The BRYAN® Disc

Galbusera et al. published their review in March 2006 of the biomechanics and kinematics at the C5–C6 spinal unit both before and after placement of a BRYAN® Cervical Prosthesis (Galbusera et al. 2006). In this study, the authors produced a finite element (FE) model of the functional spinal unit at C5–C6. The model employed reconstruction of both the vertebral bodies at C5 and C6 and representations of the vertebra, ligaments, and

discs at this level. The authors applied motion through the intact FSU to assess several kinematic measures with a compression preload. The kinematic measures studied included flexion/extension moments, pure lateral bending moments, and a pure torsion moment. They reviewed their results comparing this to known data from prior publications. The FE model was then modified to include the placement of the BRYAN® Arthroplasty Device with repeat stimulations.

The authors noted that they were able to calculate the instantaneous center of rotation of C5 with respect to C6 throughout flexion/extension. In general, FSU rotation curves post-arthroplasty were comparable to those obtained from the intact FSU with the exception of a slightly greater stiffness that was noted to be "induced by the artificial disc" (Galbusera et al. 2006). Pre- and post-arthroplasty data suggested that the position of the instantaneous center of rotation was similar in both models and was stable throughout flexion and extension – being confined to a small area "corresponding to the physiological region in both models" (Galbusera et al. 2006).

Galbusera et al. later published a more detailed finite element model from C4 to C7 expanding upon their 2006 study (Galbusera et al. 2008). In this study the group produced a finite element model including functional spinal units and appropriate soft tissue structures from C4 to C7 for kinematic testing in flexion and extension. Once again, a BRYAN® Disc Prosthesis was inserted at the C5–C6 level. Pre- and post-placement motions were analyzed. Once again, in both flexion and extension, placement of the BRYAN® Disc Prosthesis showed that there was a "general preservation of the forces transmitted through the facet joints" and that "calculated segmental motion was preserved after disc arthroplasty" (Galbusera et al. 2008). Similar to the prior study, the instantaneous centers of rotation (ICR) in flexion and extension showed preservation pre- and post-placement of the BRYAN® Disc.

This study did suggest some post-placement asymmetry in flexion and extension that the authors summarized may be secondary to lack of the anterior longitudinal ligament post-prosthesis placement. However, they were able to conclude that disc arthroplasty with the BRYAN® Disc in this multi-FSU model reproduced "near physiological motion" at the C5–C6 level (Galbusera et al. 2008).

Pickett et al. have also described the kinematics of the cervical spine following implantation of the BRYAN® Cervical Disc (Pickett et al. 2005). In this prospective cohort study, the authors described a total of 20 patients who underwent single- or two-level implantation of the BRYAN® Disc. Each of these patients was treated per protocol for a degenerative condition of the cervical discs that was producing neurologic symptoms including radiculopathy and/or myelopathy. From a kinematic standpoint, this study examined pre- and postsurgical plain radiographs including neutral lateral as well as flexion and extension radiographs at prescribed intervals. Kinematic parameters including rotation, horizontal translation, change in disc height, and center of rotation at each spinal level were evaluated using quantitative motion analysis software produced by Medical Metrics Corporation (Houston, Texas).

The authors demonstrated a postsurgical preservation of range of motion at the operated spinal segment with a mean postsurgical range of motion of 7.8° at the 24-month postsurgical follow-up. They noted that disc placement "either placed at C5–6 or C6–7" seemed to change the "relative contribution of each spinal segment to overall sagittal rotation (DiAngelo et al. 2004)." They also noted that total overall cervical motion as measured from C2 to C7 was increased at late follow-up intervals. There were no significant changes in sagittal rotation, anterior-posterior disc height, translation, or center of rotation following placement of the BRYAN® Arthroplasty Device at the follow-up intervals. The authors concluded that placement of BRYAN® Artificial Disc for cervical radiculopathy and or myelopathy appears to "reproduce the preoperative kinematics of the spondylotic disc (Pickett et al. 2005)." This in vivo study tends to support the finite element studies noted earlier as published by Galbusera et al. (2006, 2008).

Rick Sasso and Natalie Best published a novel BRYAN® Disc article in February 2008 analyzing

radiographic data from patients who had undergone either ACDF with allograft and plating or placement of a single-level BRYAN® Cervical Disc (Sasso and Best 2008). In this single-level study, all patients had radiographic follow-ups immediately preoperatively as well as postoperatively at regular intervals up to a 24-month endpoint. The study represents data from a subset of patients involved in the randomized prospective BRYAN® Cervical Disc Arthroplasty study for the US FDA. The authors evaluated flexion/extension and neutral lateral radiographs at the prescribed intervals and analyzed motion using Medical Metrics software similar to that described in the prior chapter by Pickett et al. (2005). They quantified functional spinal unit motion, translation, and center of rotation.

As expected, there was significantly more motion in flexion and extension in the disc replacement group than in the fusion group at the index surgical level. In this study, the arthroplasty FSUs were able to retain an average range of motion of 6.7° at the 24-month follow-up interval. This was in contrast to the range of motion of the fusion group which was initially 2.0° at the 3-month follow-up, decreasing overtime to 0.6° at the final 24-month follow-up. The authors also noted that flexion/extension both above and below the operative level was not statistically different in those groups having undergone cervical arthroplasty versus fusion. An interesting finding, however, is that mobility overall increased for both groups over time. At levels above the fusion, there was an increase in translation in comparison to the arthroplasty device which showed no evidence of an increase in translation at the adjacent level. The finding of increased translation was only statistically significant at the 6-month follow-up interval. The authors concluded that the BRYAN® Disc appeared to preserve preoperative kinematics at adjacent levels in comparison to fusion which showed some changes overall in the kinematics (Sasso and Best 2008). This did support the postulation that arthroplasty has the potential to preserve cervical kinematics at adjacent levels postoperatively.

Sasso et al. also reported upon the motion analysis/kinematic properties of all patients enrolled in a prospective randomized multicenter trial for the BRYAN® Cervical Artificial Disc Prosthesis (Sasso et al. 2008). Their overall objective in this study was to analyze the entire set of patients in a prospective fashion similar to the subset which was previously reported (Sasso and Best 2008). In this study, all patients received either a single-level ACDF or a single-level disc arthroplasty with the BRYAN® Cervical Disc Prosthesis. A total of 221 patients received fusion, whereas 242 received a single-level arthroplasty. Operative segments could include the C3–4 disc space down to the C6–7 disc space. Similar to the previous subset, the authors analyzed flexion/extension and neutral lateral radiographs obtained at prescribed intervals postoperatively in comparison to the preoperative interval. This study examined patients up to and including the 24-month interval. Medical Metrics software was once again used to track the cervical vertebral bodies at the index FSU looking at flexion and extension range of motion as well as translation.

Similar to the prior subset, the arthroplasty group retained statistically significant increases in motion at the index FSU in comparison to the ACDF group. The arthroplasty group had an average of 7.95° of motion at the 24-month follow-up. The preoperative range of motion at the same FSUs was 6.43° with no significant evidence of degeneration of motion at the same FSU following arthroplasty at the 24-month interval. As expected, average range of motion in the fusion group slowly diminished to the point of being 0.87° at 24 months. Preoperatively this group had a range of motion of 8.39°. Also noted was no evidence of BRYAN® Disc migration or subsidence at the 24-month follow-up – suggesting that the arthroplasty device was functioning as designed at this early follow-up interval and reproducing the kinematics of the degenerative disc space at the index FSU in comparison to fusion of those same levels.

The PRODISC-C®

DiAngelo et al. have examined the in vitro biomechanics of the PRODISC-C (DiAngelo et al. 2004). Their study was designed to compare disc

arthroplasty to ACDF in cervical spine biomechanics in a multilevel human cadaveric model. This study employed three spinal conditions: intact harvested specimens alone, single-level arthroplasty specimens, and single-level fusion specimens. The study incorporated a total of six fresh human cadaveric specimens harvested from C2 to T1. All specimens were treated according to the group assigned at the C5–6 level following testing in their intact condition. This study simulated fusion in a unique way. Fusion was accomplished across the treated spinal level via custom designed fixtures similar to an external fixation system. Following surgical treatment according to protocols, kinematic principals were tested under biomechanical loading devices. This was done with a programmable testing apparatus that "replicated physiologic flexion/extension, lateral bending, and axial rotation (DiAngelo et al. 2004)." The authors then measured vertebral motion via applied load and bending moments.

As expected, the simulated fusion was successfully able to diminish motion at the treated level relative to the harvested untreated as well as disc arthroplasty conditions. The authors noted that adjacent segment motion increased in those specimens following the reduction of motion at the simulated fusion segment. This study noted that in all modes of testing, the PRODISC-C arthroplasty device "did not alter the motion patterns at either the instrumented level or adjacent segments compared with the harvested condition except in extension (DiAngelo et al. 2004)."

Puttlitz et al. have examined post-disc arthroplasty kinematics using the PRODISC-C in a human cadaveric model (Puttlitz et al. 2004). This study utilized a total of six fresh frozen human cadaveric spines to evaluate two different spinal conditions including both the intact and post-disc arthroplasty condition at the C4–C5 level. Prior to testing, compression and a follower load were applied, as well as pure moment loading to the specimens to evaluate treatment kinematics and pretreatment kinematics. Range of motion (ROM) kinematics was then measured using an optical tracking system, and data was reported.

The results of this limited cadaveric study suggest that the PRODISC-C was able to retain "approximate" intact motion in all three rotation planes "flexion/extension, rotation, and lateral bending (Puttlitz et al. 2004)." They also examined coupled rotations including lateral bending during axial rotation and axial rotation during lateral bending – noting no significant difference in these two tested conditions following arthroplasty. They concluded that ball-and-socket devices such as the PRODISC-C can "replicate physiologic motion at the affected and adjacent levels (Puttlitz et al. 2004)." This is the only study on the PRODISC-C that examines a motion coupling from a kinematic standpoint and suggests maintenance of the coupled motions following cervical arthroplasty. It is possible that a larger in vitro study could provide further insight into the coupling motions examined in this study that were novel to it.

Combined PRODISC-C®/PRESTIGE® ST/LP Studies

Chang et al. have looked at both the PRODISC-C® and PRESTIGE® Artificial Devices compared with ACDF in a cadaveric model (Chang et al. 2007a). The object of the authors' investigation was to examine cervical kinematics at surgically treated levels as well as adjacent segments in a cadaveric model – evaluating two different types of cervical artificial disc devices in comparison to the intact spine and a fusion model. For the purposes of this study, a total of 18 cadaveric human spines were tested in their intact state with kinematic modes including flexion/extension, axial rotation, and lateral bending. These three groups of specimens were then subjected to a surgical intervention including placement of a PRODISC-C®, a PRESTIGE II® Artificial Disc, or ACDF. All specimens were operated at the C6–7 level. This study simulated ACDF with placement of a 7 mm tapered cortical allograft followed by placement of a rigid anterior cervical plate and screws "to maintain lordosis at the treated level (Chang et al. 2007a)." Placement of either the PRESTIGE® or the PRODISC®

device was performed according to the manufacturers' recommended surgical technique at the C6–7 level.

Range of motion was noted to increase after arthroplasty in comparison with the intact spine in extension in both the PRODISC-C® and PRESTIGE® groups as well as in flexion in both arthroplasty groups. With respect to bending, the post-arthroplasty ROMs were greater than those of the intact spine in both arthroplasty groups; this was also similar for rotation. Adjacent level ROM was noted to decrease in all specimens that underwent implantation of a cervical arthroplasty device for all tested kinematic modes. With respect to ROM adjacent to the fusion-treated spines, it was noted to diminish in all motion modes at the treated level but increase at all adjacent levels with a reported range of 3–20%. Adjacent level range of motion diminished in all modes post-arthroplasty with the exception of extension in those patients who underwent a total disc arthroplasty.

This study lends additional credence to the idea of adjacent level disease as a result of surgery as noted by the increased range of motion kinematics at adjacent levels in those cadaveric specimens undergoing ACDF in comparison to the diminished range of motion noted in those patients undergoing cervical disc arthroplasty.

Chang et al. have also evaluated adjacent level disc pressure and facet joint forces after cervical arthroplasty with the PRODISC-C®/PRESTIGE® devices in comparison to ACDF in an in vitro human cadaveric model (Chang et al. 2007b). In this study, the authors examined intradiscal pressures at adjacent levels, as well as facet joint stress following both arthroplasty and cervical spine fusion in 24 human cadaveric spines obtained from C3 to T2. This study examined a surgical intervention at C6–7 in 18 of these specimens. Six specimens were excluded from the original 24 in the study based upon pre-procedural radiographic studies suggesting bone abnormalities. This study examined intradiscal pressures with pressure transducer needles. The forces in the facets, however, were indirectly measured.

The specimens were then divided into three groups with six specimens per group – each receiving either an artificial disc implantation (PRODISC-C® or PRESTIGE®) or in the case of the third group an ACDF. With respect to the PRODISC-C® group, a 7 mm height disc was chosen, and with respect to the PRESTIGE® group, an 8 mm height disc was chosen. These were determined to be "adequate for the cadaveric specimens (Chang et al. 2007b)." The fusion groups, as per a previous study reported by Chang et al. (Rousseau et al. 2008), underwent fusion with a 7 mm lordotic tapered allograft fixed with a rigid plate and screw.

Biomechanical testing ensued with flexion/extension, lateral bending, and axial rotation modes measured. In the arthroplasty-treated specimens, the intradiscal pressure was not significantly different in comparison to the intact spine at adjacent levels proximal and distal to the arthroplasty FSU. However, in those specimens treated with fusions, the intradiscal pressures increased at the location of the posterior annulus fibrosus in extension and at the location of anterior annulus in flexion at the cranial adjacent level. At the caudal adjacent level intradiscal pressure change was not noted to be significant. Indirect measurements of facet forces were computed in this study and were noted to be minimal in flexion, bending, and rotation modes in both arthroplasty- and fusion-treated spines. In extension the arthroplasty models exhibited an increase in facet forces at the treated FSUs in comparison to the fusion model where the facet forces decreased at the treated FSU and increased at the adjacent segments (Chang et al. 2007b).

Rousseau et al. undertook an in vivo analysis of two types of ball-and-socket cervical disc devices which they classified as "two-piece implants (Rousseau et al. 2008)." The authors of this study considered three-piece implants to be those with a mobile nucleus between two metal implants. They examined a total of 26 patients who had been implanted with the PRESTIGE® LP Device and compared them to 25 patients who had been implanted with the PRODISC-C® Device. Investigational specimens were then referenced against the measurements of 200 healthy cervical discs in vivo. Spineview™ software (Surgiview, Paris, France) was used to

calculate the intervertebral range of motion and the mean center of rotation kinematic variables. The authors also calculated the center of rotation between full flexion and extension for range of motion.

In comparison to the normal non-implanted vertebral discs, the range of motion kinematics in flexion and extension were noted to be significantly reduced with both types of arthroplasty. Comparing the two arthroplasty groups head to head, range of motion was similar, and the location of the center of rotation with full flexion and extension appeared to be "influenced by the type of intervertebral disc despite interindividual variability (Rousseau et al. 2008)." Specifically, the authors noted that there was a trend toward a "more anterior and superior" location of the center of rotation in full flexion and extension with the prosthetic devices then observed in normal nonoperated control discs (Rousseau et al. 2008). This comparison of two-piece ball-and-socket-type prosthesis was notable for the fact that neither cranial nor caudal types of device designs were able to fully restore flexion and extension kinematics to normal mobility in the kinematic measurements described in the study including range of motion and center of rotation.

The PRESTIGE® Disc

DiAngelo et al. have described an in vitro biomechanical study comparing non-fusion (intact specimen) to ACDF and cervical arthroplasty in a multilevel human cadaveric model (DiAngelo et al. 2003). The study was conducted using a programmable testing apparatus that allowed for replication of physiologic flexion/extension and lateral bending. The authors measured vertebral motion applied load and bending moments. The authors used the PRESTIGE® ST cervical joint for arthroplasty and an Orion® (Medtronic Sofamor Danek, Memphis, TN) plate to simulate fusion in this small cadaveric study. Included were a total of four fresh human cadaveric specimens harvested to include C2–T1.

Following their measurements, they reported findings. The application of an anterior cervical plate significantly decreased the motion across the fusion site relative to the native or artificial joint conditions. The placement of a PRESTIGE® artificial cervical joint "did not alter the motion patterns at either the instrumented level or the adjacent segments compared with the harvested condition (DiAngelo et al. 2003)." This study of kinematics is novel not only in the maintenance of normal range of motion at the implanted FSU but also with regard to maintenance of normal motion at all segments of the spine status post-placement of a PRESTIGE® cervical disc prosthesis. Unfortunately, this small in vitro study did not have the power ability to make large in vitro analyses.

The PCM® Disc

Several novel kinematic studies have been performed with regard to the PCM® Device. The device has undergone basic testing from a kinematic standpoint (Hu et al. 2006) in addition to studies that add to the basic kinematic studies in novel ways (McAfee et al. 2003; Dmitriev et al. 2005). These have included studies that examine the role of the posterior longitudinal ligament (PLL) and those that measure adjacent level intradiscal pressures following placement of the PCM® Device (Hu et al. 2006; McAfee et al. 2003; Dmitriev et al. 2005).

Hu et al. have examined the PCM® arthroplasty device, evaluating biomechanical as well as other factors, in a caprine animal model (Hu et al. 2006). The PCM® Disc was tested in vivo and ex vivo in 12 goats divided into 2 distinct groups. These two groups differed in their survival periods – 6 and 12 months, respectively. Each specimen underwent an anterior discectomy at the level C3–C4 followed by implantation of the PCM® Device. Outcomes of the study were based upon examination of the prosthesis by computerized tomography, multidirectional post-sacrifice flexibility testing, decalcified histology, and histomorphometric and immunochemical analyses.

With regard to postoperative survival, there was no evidence of prosthesis loosening at the

two examined survival periods. Multidirectional flexibility testing from a kinematic standpoint was performed in all standard measures. Under axial rotation and lateral bending, there was no significant difference in the range of motion of the operated FSU in comparison to nonoperative controls. The authors concluded that intervertebral range of motion was preserved under axial rotation and lateral bending at the two examined postsurgical time frames in this animal mode (Hu et al. 2006).

McAfee et al. established that the posterior longitudinal ligament (PLL) may provide a stabilizing influence to the cervical spinal segment (McAfee et al. 2003). Biomechanical testing was performed using human cadaveric spines and a six-degree-of-freedom spine simulator with additional optoelectronic motion measurement. The major finding was that biomechanical stability may be restored following complete anterior cervical discectomy with resection of the PLL via implantation of an arthroplasty device such as the PCM® Device.

Dmitriev et al. have looked at intradiscal pressure and segmental kinematics following cervical disc arthroplasty with a PCM® Device (Dmitriev et al. 2005). This in vitro human cadaveric study examined a total of ten spines. Each spine underwent intact analysis with subsequent reconstruction at C5–C6 with a total disc replacement, an allograft dowel, or an allograft dowel and an anterior cervical plate. The authors then tested the specimens in displacement control under axial rotation, flexion/extension, and lateral bending kinematic modes. They recorded intradiscal pressure at levels adjacent to the C5–6 space including C4–5 and C6–7 FSUs. Range of motion was monitored at the operative FSU (C5–C6).

The authors noted that the intradiscal pressures recorded at adjacent levels were similar to the intact (nonoperated) condition in those patients who had undergone a total disc replacement with the PCM® Device. However, the intradiscal pressures at C4–5 in flexion/extension for both types of simulated fusions were noted to be significantly higher than the mean intradiscal pressures measured at these same levels in the intact and disc replacement groups. Similar findings were noted at C6–7, where significantly increased intradiscal pressures were achieved in all three loading methods including axial rotation, flexion/extension, and lateral bending. As expected, both types of simulated fusions at C5–6 produced a significantly diminished range of motion during flexion/extension testing. The authors concluded that the PCM® Disc has the ability to maintain adjacent level intradiscal pressure in comparison to increased intradiscal adjacent level pressures noted with simulated fusions. This study lends some support to the concept of adjacent level disease as a result of the modified kinematic environment adjacent to a fusion.

Computer Simulation and Finite Element (FE) Modeling Studies

In addition to numerous disc-specific kinematic studies that have been published in recent years, several authors have contributed to the collective understanding of finite element (FE) modeling with respect to artificial cervical disc replacements. Ahn et al. published such a study, noting as background that there was a need for further simulation studies to understand common design themes for restoration of motion as the result of numerous types of cervical disc designs (Ahn and DiAngelo 2008). They cited the numerous examples of both constrained and semi-constrained devices. The study proposed to expand upon the limited number of in vitro studies previously discussed herein.

The study incorporated a three-dimensional graphics-based computer model of the subaxial cervical spine that had previously been developed. This model was used to study the kinematics and mechanics of an arthroplasty device placed at the C5–6 disc space – the validation for which had been described in a previous study by the same group (Ahn and DiAngelo 2008). The basic computer model incorporated the geometry of cervical vertebrae as established from the computer tomographic images of a 59-year-old woman, linking the adjacent vertebrae at C5 and C6 as a “triple joint complex

comprised of the intervertebral disc joints in the anterior region and 2 facet joints in the posterior region and the surrounding ligament structure (Ahn and DiAngelo 2008)."

The authors modeled intervertebral discs as nonlinear elements having a total of six degrees of freedom. With this model, they studied three different theoretical prosthetic disc devices. The first device tested was a disc with the center of rotation of a spherical joint located in the midportion of the C5–6 disc, the second device being with the center of rotation of the cervical joint located 6.5 mm below the midportion of the C5–6 disc, and the third being the center of rotation of the cervical joint in a plane located at the C5–6 disc level. The authors simulated removal of the anterior longitudinal ligament and the anterior portion of the annulus as well as the nucleus pulposus for placement of the disc prosthesis. They then tested the three disc implantation designs throughout the six degrees of freedom allowed by the computer model.

With the three types of disc devices, the authors noted that a constrained spherical joint (device design #1 with the joint placed at the midportion of the disc) significantly increased facet loads during cervical spine extension kinematics. Tested design #2 lowered the rotational axis of the spherical joint toward the subjacent body, and this was noted to kinematically cause a "marginal increase in facet loading during flexion, extension, and lateral bending (Ahn and DiAngelo 2008)." Unconstraining the device (device design #3) minimized facet loading buildup during all loading modes by placing the center of rotation of the spherical joint in a plane located at the C5–6 disc level.

The authors concluded that a finite element model was able to demonstrate simple design changes that may have effects on the kinematic behavior of cervical discs placed in human spines at the C5–6 disc space. They were able to predict facet loads calculated from their computer model but noted that the computer model still needs to have validation with regard to in vitro experimental studies. This model does add credence to kinematic principles of device design and goes one step beyond some of the in vitro research in its theoretical device design principles.

Liu et al. have described a fluoroscopic kinematic study looking at the kinematics of the anterior cervical discectomy fusion versus cervical artificial disc replacement at the C5–6 joint (Liu et al. 2007). In this novel study, the investigators used a controlled group of ten normal subjects as well as ten patients treated with ACDF in comparison to ten patients treated with cervical artificial disc replacement. Both types of surgical procedures were performed at the C5–6 level. Radiographic data was collected with the patient performing a full flexion and extension motion under fluoroscopy surveillance with kinematic data collection obtained from these fluoroscopic images. The data were derived based on the "inverse dynamic model of the entire cervical spine (Liu et al. 2007)." This custom model was created based on "KANE'S Dynamics and the Reduction Modeling Technique (Liu et al. 2007)." The authors then calculated kinematic data using software and reported the results.

The ACDF group had notable increases in intersegmental rotation at adjacent disc spaces (C6–7 and C4–5 levels) in comparison to the intact normal specimen. Also notable was the fact that the intact spine (no surgical intervention) had a greater range of motion than that observed in ACDF despite these increases of adjacent segment rotations in the ACDF population. The authors noted that the kinematic measurements in the cervical arthroplasty group were similar to those in the normal group and postulated (by their measurement principles) that cervical artificial disc arthroplasty has the potential to restore "normal dynamic motion of the cervical spine (Liu et al. 2007)."

This study provides a novel approach for analysis of in vivo contact forces and expands upon basic kinematic measurements that have been reported in disc arthroplasty studies. It also suggests that cervical arthroplasty has the potential to maintain adjacent segment kinematics, although it is difficult to make predictions with respect to adjacent segment degeneration as a result of this motion analysis study.

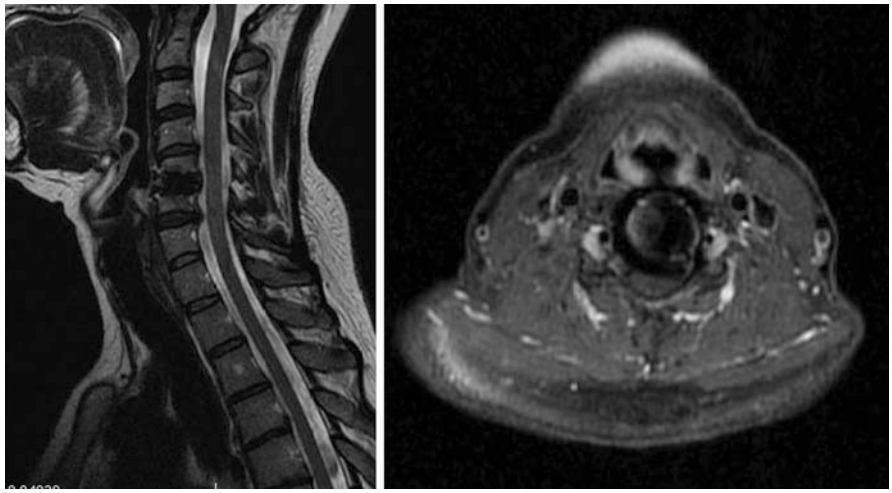

Fig. 6 The BRYAN® Cervical Disc Prosthesis is visualized on these postoperative MR sagittal and axial images. Titanium alloy devices such as the BRYAN® device may have less MRI artifact that similar devices constructed with CoCr or stainless steel. These images demonstrate the imaging characteristics of this device at the index and adjacent surgical levels. (© Courtesy of Rick Sasso, Indianapolis, IN)

Multidisc Studies

Lin et al. created a novel in vivo study to evaluate bone/implant stresses at the C5–6 disc space with placement of BRYAN®, PRESTIGE® LP, and PRODISC® Cervical Disc prostheses (Lin et al. 2009). Their image-based finite element modeling technique was designed to predict stress patterns at the interface between the prosthesis and the lower vertebral endplate – an effort to elucidate possible mechanisms of subsidence and describe load transfers of disc designs. The group built a three-dimensional finite element model of the C5–6 functional spinal unit based on computed tomographic (CT) images acquired from a patient who had previously been identified as a candidate for cervical disc arthroplasty.

The modeling process included facet joints, uncovertebral joints, and specific artificial disc designs that could be placed within the intervertebral disc space. The authors evaluated the discs and endplates in flexion/extension and lateral bending with compression applied. The authors noted that the PRODISC-C® and PRESTIGE® LP Discs caused "high stress concentrations around their central fins or teeth, which may initiate bone absorption (Lin et al. 2009)." With respect to the BRYAN® Disc, the prosthesis appeared to recover the highest range of motion secondary to what the authors described as the "high elastic nucleus" which was notable for diminishing the stresses at the superior endplate of C6 (Lin et al. 2009). The authors also noted that the PRESTIGE® LP Disc, with its rear positioned metal-metal joint, may be a concern for a mechanism of possible subsidence in the posterior aspect of this arthroplasty device.

The authors concluded that the rigidity of the nucleus/core in both the PRESTIGE® LP and the PRODISC-C® prostheses is capable of maintaining initial disc height at the consequence of high contract stresses at the bone endplate interface with either "improper placement or under sizing (Lin et al. 2009)." The BRYAN® Device differs in its core rigidity creating a much larger displacement during motion allowing for "more variation in disc height that may theoretically increase the load sharing of facet and uncovertebral joints compared to more rigid artificial disks (Lin et al. 2009)." This in vivo finite element study goes beyond typical center of rotation and flexion/extension

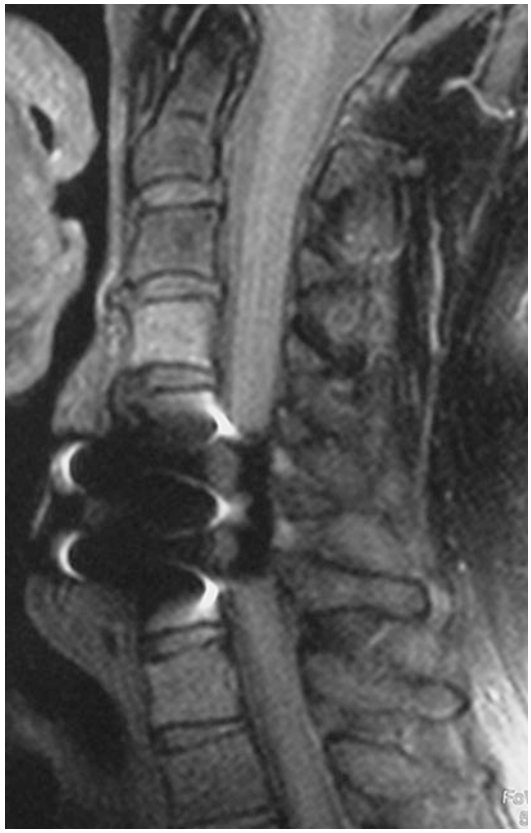

Fig. 7 The MOBI-C® is visualized on this sagittal MRI (T1/FS technique). These images demonstrate the imaging characteristics of this device at the index and adjacent surgical levels. Significant artifact is present at the index and adjacent levels making diagnostic interpretation challenging. (© Courtesy of Rick Sasso, Indianapolis, IN)

kinematics in looking at one of the major causes for implant failure, subsidence. The study is only predictive of the stresses caused by device design and does not predict ultimate subsidence mechanisms. It goes beyond prior studies in elucidating possible areas of increased device/endplate mechanical stresses that are the result of normal device kinematics.

Future Kinematic Design Principles

With respect to basic device design principles, kinematic modeling will likely have an effect on patient outcomes and adjacent segment disease in the long-term. Future design work will continue to make heavy use of preclinical modeling, FE modeling, biomechanical testing, and translational nonhuman testing. Currently implanted cohorts from US FDA trials will alter our understanding of device kinematics over the intermediate and long-term. At the time of this writing, US follow-up of these devices has been published up to 10 years (Sasso et al. 2017). Wear debris caused by device design and kinematic conflicts may play a role in device construction materials and constraint properties as we understand long-term outcomes beyond this interval. Postoperative imaging limitations will also affect future device design as in vivo human studies will continue to make heavy use of imaging techniques and measurements in lieu of biomechanical and histological techniques (Figs. 6 and 7).

Current arthroplasty designs restore only the anterior and middle columns of the cervical spine. They rely on posterior column preservation at the index surgery and over time. Future device designs may include techniques that modify not only structures at the level of the disc but also facets.

Conclusions

We sought to review the basic cervical kinematics that exist and correlate the early data reported from in vivo, in vitro, and finite element (computer-based) studies on disc arthroplasty. Device design with respect to the modified center of rotation at an FSU, device fixation to the vertebral endplates, and flexibility of the articulating nucleus all appear to play a role in reproduction of normal cervical kinematics after cervical disc arthroplasty. A number of these studies also begin to suggest kinematic means of surgical contribution to adjacent level degeneration. It is extremely encouraging to see that many kinematic studies that have been undertaken coincide with the results of US FDA-IDE trials of these devices.

Little data currently exists on how reproduction (or lack of reproduction) of normal kinematics affects intermediate- and long-term patient outcomes and adjacent segment degeneration. Abnormal kinematics may contribute to early

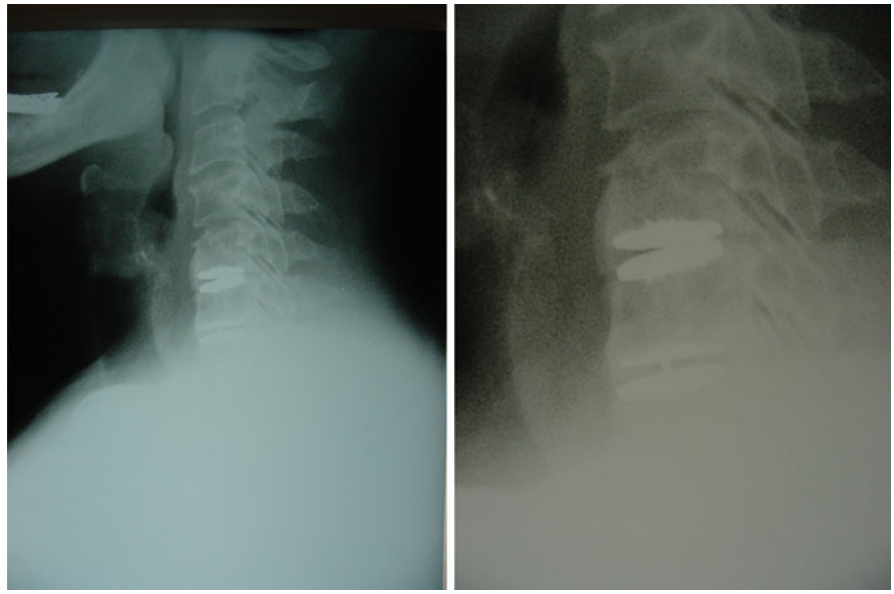

Fig. 8 The MOBI-C® is visualized on these lateral radiographic views of the cervical spine. This patient presented with loss of motion and radiographic evidence of heterotopic ossification at the index surgical levels (C5-C6 and C6-C7). These images demonstrate the imaging characteristics of this device at the index and adjacent surgical levels. Significant artifact is present at the index and adjacent levels making diagnostic interpretation challenging. (© Courtesy of Rick Sasso, Indianapolis, IN)

subsidence in some of these devices; however, other than descriptive subsidence complications in a number of clinical series, the abnormal kinematics of the devices themselves have not clearly been suggested to be at fault for such events. Several studies have suggested that cervical disc arthroplasty causes an early-term risk of heterotopic ossification (Mehren et al. 2006; Leung et al. 2005; Heidecke et al. 2008) (Fig. 8). The authors of this publication are not aware of any current kinematic studies that demonstrate or further elucidate either the biomechanical or kinematic mechanisms that may result in heterotopic ossification. Indeed, it may be that device placement/implantation techniques place patients at more risk of heterotopic ossification than properties intrinsic to the arthroplasty devices. This is supported by indirect experiential evidence of a diminished rated of heterotopic ossification in patients who have been treated with NSAIDS in some randomized prospective studies (Sasso et al. 2007a, b; Heller et al. 2009).

As cervical device design continues to proceed, it will be critical for both device designers and study investigators to understand the kinematics in the short-, intermediate-, and long-term phases of the various devices. Modified kinematics as the result of improper placement of arthroplasty devices must also be investigated. Such understanding will likely contribute to increased knowledge with respect to the long-term wear and survival of the devices and may possibly alter the patient outcomes in a positive manner.

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