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Comparative Finite Element Modeling Study of Anterior Cervical Arthrodesis Versus Cervical Arthroplasty With Bryan Disc or Prodisc C

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ABSTRACT

Introduction:

Cervical disc arthroplasty (CDA), a motion-preserving alternative to anterior cervical discectomy and fusion (ACDF), is used in military patients for the treatment of disorders such as spondylosis. Since 2007, the FDA has approved eight artificial discs. The objective of this study is to compare the biomechanics after ACDF and CDA with two FDA-approved devices of differing designs under head and head supported mass loadings.

Materials and Methods:

A previously validated osteoligamentous C2-T1 finite element model was used to simulate ACDF and two types of CDA (Bryan and Prodisc C) at the C5-C6 level. The hybrid loading protocol associated with in vivo head and head supported mass was used to apply flexion and extension loading. First, intact spine was subjected to 2 Nm of flexion extension and the range of motion (ROM) was measured. Next, for each surgical option, flexion-extension moments duplicating the same ROM as the intact spine were determined. Under these surgery-specific moments, ROM and facet force were obtained at the index level, and ROM, facet force, and intradiscal pressure at the rostral and caudal adjacent levels.

Results:

ACDF led to increased motion, force and pressures at the adjacent levels. Prodisc C led to increased motion and facet force at the index level, and decreased motion, facet force, and intradiscal pressure at both adjacent levels. Bryan produced less dramatic biomechanical alterations compared with ACDF and Prodisc C. Numerical results are given in the article.

Conclusions:

Recognizing that ROM is a clinical measure of spine stability/performance, CDA demonstrates a more physiological biomechanical response than ACDF, although the exact pattern depends on the implant design. Anterior and posterior column load-sharing patterns were different between the two implants and may affect implant selection based on the anatomical and pathological state at the index and adjacent levels.

INTRODUCTION

Anterior cervical discectomy and fusion (ACDF) is one of the most common spinal operations in the USA for both civilian and military patients, with more than 150,000 cases being performed annually.[1–4] It is indicated for cervical spine degeneration causing radiculopathy and/or myelopathy, as well as spinal instability, and neck pain. The C5-C6 segment is the most commonly operated level in civilian and military populations.[5–12] This is followed by the C6-C7 segment. Appendix 1 provides a brief review on the most commonly operated cervical spinal level in military patients that include active duty pilots. Sample sizes ranged from 12 to 282 in these studies. One important adverse outcome is adjacent segment degeneration. This is when the adjacent segments undergo degeneration because of increased stress, sometimes requiring revision surgery. Cervical disc arthroplasty (CDA) is a recent alternative to this conventional procedure (ACDF), and it consists of implanting an artificial disc after the removal of the original disc. It is a motion preserving strategy that could maintain motion at the index segment and decreases the likelihood of adjacent segment degeneration. A number of artificial discs approved by the FDA are on the market for cervical arthroplasty, since the first approval in the year 2007. The designs of the implant vary widely in terms of permissive translation of the center of rotation (unconstrained versus constrained), allowable range of motion (ROM; flexion extension, rotation, and lateral bending), materials (titanium, cobalt-chromium alloy, polyethylene, and polyurethane), number of moving pieces (one to three), and enclosure of the moving parts (open versus closed design). There is a lack of

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studies that directly compare the biomechanics of intact spine, conventional fusion (ACDF), and CDA with different designs under the in vivo head weight and head supported mass.

Finite element analysis can provide information that is otherwise unobtainable from clinical and cadaveric studies. Cadaveric studies are invariably susceptible to biodegradation. Depending on the condition of the biological tissue, experimental results may vary. Even for the same specimen, the results may vary depending on the type of loading applied to the spine and its state: intact, fusion, and CDA. Both cadaveric and clinical studies may have confounding factors since there are biological and morphometric variables. The intrinsic biomechanical properties cannot be obtained from human subjects because of their invasive nature, such as intradiscal pressure and facet force. Finite element models allow for selective variation of biological or surgical parameter in question and can apply the same level/magnitude of loading and reproduce experiments without involving biodegradation. Finite element modeling permits to extract the extrinsic (ROM) and intrinsic parameter (disc pressure and facet force) metrics, which are not feasible using in vivo human subjects.

Clinical studies in the civilian literature have shown motion preservation after CDA.[13,14] Clinical studies have consistently shown that the ROM at the index level is greater with CDA than ACDF. This motion preservation is the core principle of CDA. For example, a prospective multicenter clinical trial with 103 patients with single-level Prodisc C CDA reported the average flexion-extension ROM to be 8.5 degrees preoperatively and 8.1 degrees at 7 years.[13] A prospective randomized controlled study of 128 Bryan CDA patients showed that the mean ROM was 6.5 degrees preoperatively and this was 8.7 degrees at 10 years, compared with 0.6 degrees for the ACDF group (decreased from 8.3 degrees).[14] Another clinical study with Bryan disc showed motion at the index level in 93% of patients at 5 years and 56% even at 18 years after surgery.[4]

FDA has approved eight CDA devices for use in civilian and military patients. There is a lack, however, of nonindustry sponsored studies comparing CDA against conventional fusion.[15] A review of military studies shows that there is a paucity of studies that directly address the unique biomechanical conditions in the military population—healthy, young subjects with a head supported mass. For example, in a military-specific study of CDA, the authors focused on the rate of return to military duty and clinical outcomes.[10,16] Biomechanical quantifications were not made because of the study design. Another study stated: “With the exception of Tumialan who also reported on the military occupational specialty of his 12 CDA patients with an average return to duty time of 10.3 weeks, the other studies focus on clinical outcomes with little to no emphasis on military occupational outcomes.”[6] Another military study reported the clinical outcomes from 34 CDA military patients and did not include biomechanical quantifications.[7] Previous military literature demonstrated that there is a significant biomechanical and physiologic impact with head supported mass: helmet and night vision goggles.[4] The cited reference, based on studies from its references 41 and 43, stated that helmets can range in mass from 1.31 to 2.15 kg for fast-jet aircrew and as much as 3.7 kg for a helicopter flight helmet equipped with night vision goggles.[17]

The biomechanical alterations at the index and adjacent segments after ACDF and CDA with FDA-approved Bryan and Prodisc C implants were evaluated using finite element modeling. The Bryan disc was chosen to represent a design philosophy that mostly closely mimics the natural anatomy. This implant is an unconstrained cervical artificial disc with no fixed center of rotation and has a one-piece encapsulated design with a polyurethane membrane (annulus fibrosus) and a saline-filled core (nucleus pulposus). On the other hand, the Prodisc C implant contains a fixed center of rotation in the form of a polymer core rigidly fixed to the inferior metal plate. The superior metal plate acts as a socket that glides over the polymer ball (ball and socket design) in an open design (no encapsulating polymer membrane). These two CDA devices represent vastly different design strategies. Specifically, the research questions were (1) how do motion, facet load, and intradiscal pressure at the adjacent levels differ for ACDF and two types of CDA under flexion and extension with simulated head supported mass and (2) under the same loading, how do the ROM and facet load at the index level differ for ACDF and two types of CDA?

METHODS

A previously published osteoligamentous spine model was used in the present study.[18,19] The model consisted of seven segments (C2-T1) meshed with hexahedral elements with material properties obtained from the literature (Appendix 2). The model simulated the cancellous core and cortical shell of the body, laminae, pedicles and spinous processes, annulus fibers, ground substance, and nucleus pulposus, anterior and posterior ligaments of the disc and facet joints, ligamentum flavum, and interspinous ligaments. The subaxial column was meshed with hexahedral elements, and materials properties were obtained from the literature.[20–22] The vertebral body had a cortical thin shell, a softer trabecular bone, endplate, posterior bone structures. The cortical bone was modeled as a linear isotropic material of 0.5-mm thick shell surrounding the trabecular bone and a 0.2-mm thick endplate was placed on the superior and inferior surface of the intervertebral disc.

The intervertebral discs were meshed with an anteroposterior asymmetry that arises because of the posteriorly displaced nucleus in cervical spine segments.[23] The anterior region of the annulus fibrosus consisted of 16 layers and the posterior region consisted of eight layers. The anterior annulus fibers did not form a continuous ring with the posterior annulus fibers; however, a gap was formed bilaterally at the uncovertebral clefts. The hyperelastic foam ground substance was defined using the Hill strain energy function. The fibers were defined using membrane elements with tension-only directional fibers embedded in the ground substance. The fibers

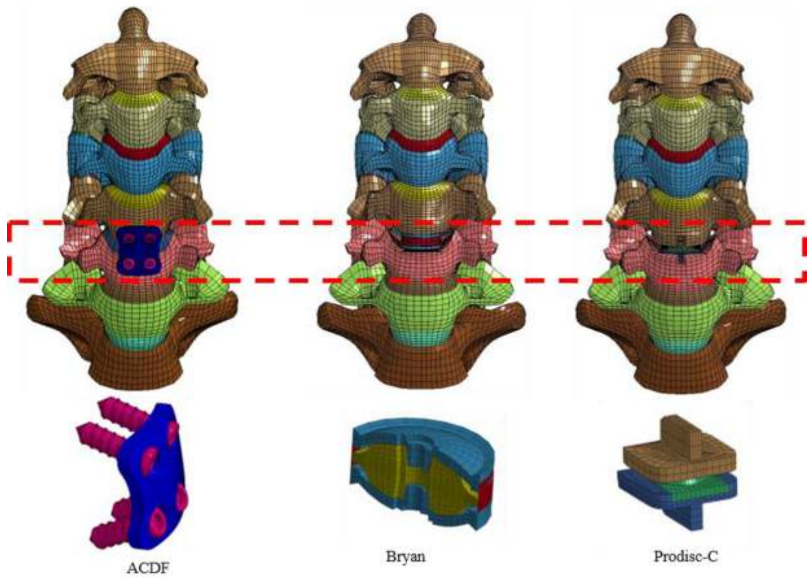

FIGURE 1. Finite element modeling of C5-6 anterior cervical discectomy and fusion (ACDF), Bryan and Prodisc C (from left to right).

in the anterior annulus were defined in a crisscross manner, whereas fibers in the posterior region were defined in the vertical direction. The ligament material property was defined using nonlinear rate dependent stress-strain relationships derived from force–displacement relationships of the cervical spine ligaments.[24]

The C2-T1 finite element model was modified at the C5-C6 functional spine unit to simulate the biomechanics of ACDF and two types of CDA devices. The standard surgical procedure was used to simulate CDA and ACDF at the C5-C6 level (Fig. 1). The anterior longitudinal ligament was removed at the surgical level in both cases. In the case of CDA, a cavity was created at the implanted level for the placement of the disc prosthesis. Both the superior and inferior components of the CDAs were attached to the respective vertebral bodies using tied contact to simulate complete osteointegration of the implant with the bone to ensure no relative motion between the implant and vertebral endplates. The contact between the metal and polymer surfaces was modeled as a surface-to-surface contact definition with a coefficient of friction of 0.1. In the case of ACDF, the disc properties were altered at the surgical level to simulate the trabecular bone, and this represented complete fusion.

Prodisc C or Bryan disc was implanted into the model for the CDA groups. The Prodisc C model consisted of two cobalt chrome alloy endplates and a core made of ultra-high molecular weight polyethylene. The Bryan disc model consisted of upper and lower titanium endplates connected by a polyurethane membrane containing a saline-filled core. The surface to surface contact was applied between the moving segments of the discs, and a tied contact condition was defined at the bone-implant interface.

All the finite element models were fixed at the first thoracic vertebra in all degrees of freedom, and the load was applied at the superior endplate the axis vertebra. Pure moment loading at 2 Nm magnitude under flexion and extension was applied to the four groups (intact, anterior cervical arthrodesis-ACDF, Bryan disc, and Prodisc C). The ROM was measured at each level and across the C3-C7 levels. The variable moment loading protocol (otherwise known as hybrid loading) was next applied. The bending moment was varied until the anterior cervical arthrodesis-ACDF, Bryan disc, and Prodisc C models displayed the same total ROM across the C3-C7 levels (although individual segments could have different ROM) as the intact model under 2 Nm of loading. A follower force simulating the small female in vivo head mass and added head supported mass comprising of a medium size army combat helmet with night vision goggles was also included as a part of the load application. Mass data were obtained from a military study conducted by LaFiandra et al. in 2007, titled: "The effects of the personal armor system for ground troops and the advanced combat helmet with and without portable visual search-night vision goggles on neck biomechanics during dismounted soldier movements." The ROM and facet force were determined at the index level under flexion and extension. The facet force was defined as the peak compressive force at the facet contact surface. The ROM, intradiscal pressure, and facet force were obtained at the adjacent segments under the same loading mode.

RESULTS

Moments required to achieve the same ROM across the C3-C7 levels in the intact model are as follows: (3.5 Nm for flexion and 4 Nm for extension), the Bryan disc (2.4 Nm for flexion and 2.2 Nm for extension), and the Prodisc C (1.8 Nm for flexion and 1.4 Nm for extension).

Index Level Biomechanics

The ROM decreased by 94.2% under flexion and 95.7% under extension after ACDF (Fig. 2). The Bryan disc decreased the ROM by 30.2% under flexion and by 3.3% under extension. The Prodisc C increased both flexion and extension ROMs by 15.9% and 24.72%, respectively. The facet forces decreased after ACDF at the index segment by 46.5% under extension (Fig. 3). The facet forces increased by 13.0% and 183.9% under extension with the Bryan disc and Prodisc C, respectively. The facets did not demonstrate any loading because of the absence of contact between the superior and inferior facets in flexion.

Adjacent Level Biomechanics in Flexion

The ROM increased by 32.7% at C4-C5 and 18.2% at the C6-C7 level after ACDF. The Bryan disc increased the C4-C5 ROM by 13.7% and the C6-C7 ROM by 10.6% (Fig. 2). The Prodisc C decreased the C4-C5 ROM by 9.0% and the C6-C7 ROM by 7.2%. The intradiscal pressure increased by 39.3% at the C4-C5 level and by 27.4% at the C6-C7 level after ACDF (Fig. 4). The Bryan disc arthroplasty increased the intradiscal pressure by 21.1% at the C4-C5 level and by 16.4% at the C6-C7 level. The Prodisc C arthroplasty decreased the intradiscal pressure by 19.8% at the C4-C5 level and by 12.9% at the C6-C7 level.

Adjacent Level Biomechanics in Extension

Anterior cervical discectomy and fusion raised the ROM by 19.2% at the C4-C5 level and 24.8% at C6-C7 level. The Bryan disc increased the ROM by 2.1% at the C4-C5 level and 4.7% at the C6-C7 level (Fig. 2). The Prodisc C decreased the ROM by 9.6% at the C4-C5 and 13.2% at the C6-C7 level. The facet forces increased by 28.4% at the C4-C5 and 35.0% at the C6-C7 after ACDF (Fig. 3). The Bryan disc increased the

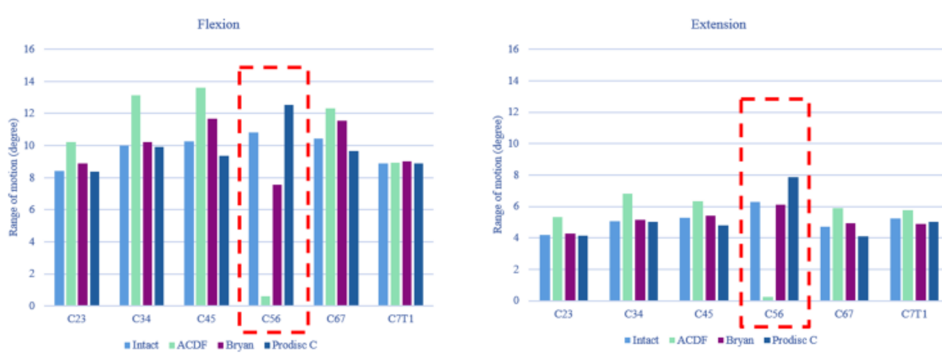

FIGURE 2. Range of motion under variable moment loading for intact and surgically altered spines under flexion and extension. ACDF, anterior cervical discectomy and fusion.

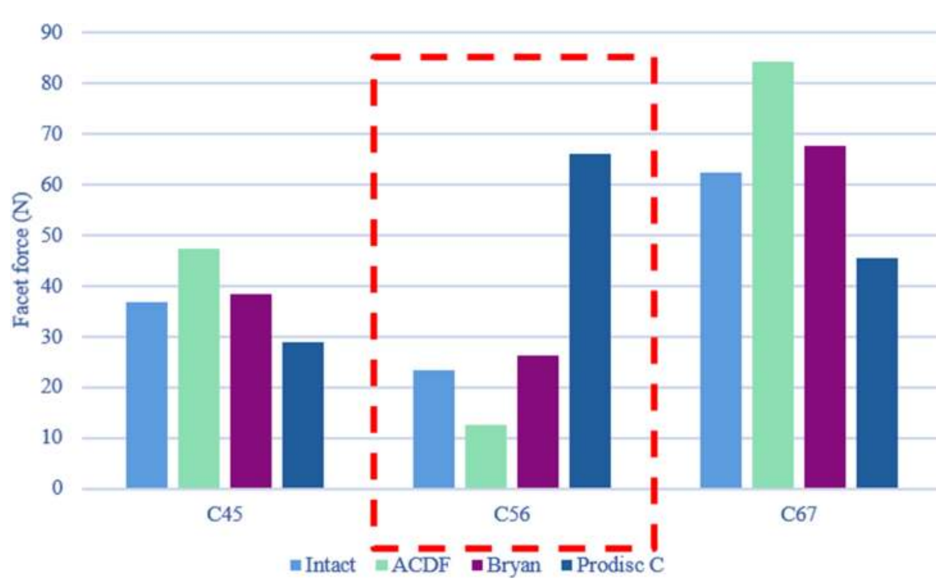

FIGURE 3. Facet force under variable moment loading for intact and surgically altered spines under flexion and extension. ACDF, anterior cervical discectomy and fusion.

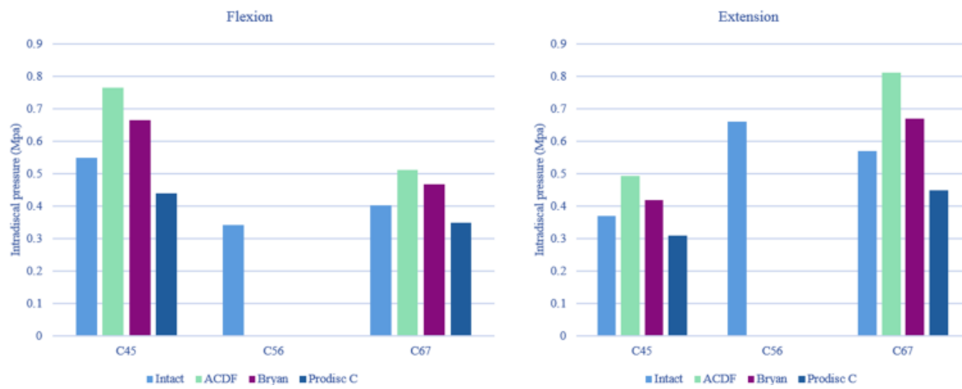

FIGURE 4. Intradiscal pressure under variable moment loading for intact and surgically altered spines under flexion and extension. ACDF, anterior cervical discectomy and fusion.

facet forces by 4.5% at the C4-C5 and 8.3% at the C6-C7 levels. The Prodisc C decreased the facet forces by 21.4% at the C4-C5 and 27.3% at the C6-C7 levels. The intradiscal pressure increased by 33.5% at the C4-C5 level and 42.5% at the C6-C7 level after fusion (Fig. 4). The Bryan disc arthroplasty increased the intradiscal pressure by 13.5% at the C4-C5 and 17.5% at the C6-C7 levels. The Prodisc C reduced the pressure by 16.2% at the C4-C5 and 21.0% at the C6-C7 levels.

DISCUSSION

Anterior Cervical Discectomy and Fusion

Anterior cervical discectomy and fusion almost eliminated motion at the index level, whereas it increased motion at the adjacent rostral and caudal levels. The facet force decreased at the index level, but it increased significantly at the adjacent levels along with the intradiscal pressure, which could contribute to adjacent segment degeneration. This is consistent with the published human cadaver and finite element literature.[25–27] Li and colleagues studied the distribution of force at the adjacent facet joints after ACDF in six C2-C7 human cadaveric spine specimens.[25] Flexion and extension bending moments were applied with a 2 Nm pure moment utilizing a 6-degree robot arm. The Tecsan pressure test system demonstrated that the adjacent segment facet joint forces experienced higher pressures, especially in extension, and the forces rose faster than the intact specimen. Qi and Lewis subjected their C1-C7 finite element model to compressive force and 1 Nm pure moment and compared ACDF with a generic unconstrained CDA (endplates and a mobile core).[26] Their fusion model demonstrated a 91% decrease in the ROM at the index level under flexion and extension, whereas the ROM increased as much as 200% at the adjacent levels. Faizan and colleagues subjected their C3-C7 finite element model to the same compressive force and up to 2 Nm of pure moment to study ACDF and CDA at C4-C6 levels.[27] The ROM at adjacent levels was approximately twice that of the intact spine. The Von Mises stresses at the adjacent endplates increased by approximately 4-fold compared with the normal spine. The findings from our study and the literature confirm that although conventional fusion protects the index level, it may lead to unfavorable biomechanical conditions at the adjacent levels.

Cervical Disc Arthroplasty With Prodisc C

Prodisc C, on the other hand, demonstrated biomechanical changes at the index and adjacent levels opposite to those seen after ACDF. This resulted in supra-physiological ROM at the index level, while decreasing motion at the adjacent levels. Although it protected the adjacent levels by reducing the facet force, intradiscal pressure and ROM, Prodisc C almost doubled the facet force under extension at the index level, compared with an uninstrumented spine. The ROM also increased at the index level after CDA with Prodisc C, although not as dramatically. The dramatic increase in the facet force supports the clinical contraindication of facet arthropathy when considering cervical arthroplasty. Patel and colleagues also found increased facet contact force and ROM at the index level under extension after CDA with Prodisc C using ten human cadaver C2-C7 specimens.[28] Bauman and colleagues conducted a study with seven human cadaver C2-T1 osteoligamentous specimens, and found increased ROM and higher peak facet pressures under extension and flexion after Prodisc C implantation compared with the intact spine (although the change in facet pressure was lower for the CDA group).[29] They also found that the facets came into contact faster and earlier after the CDA. The change in facet joint contact mechanics in addition to the increased forces and ROM could predispose the index facet joints to arthropathy and neck pain. This could be a contraindication in patients who may be exposed to higher activity levels, similar to those in the operational military environments.

Prodisc C is an open two-piece design with coupled motion rotational translation, i.e., translation is allowed only when coupled with rotation. It has a fixed center of rotation without translation. The location of the center of rotation is an important factor in spine biomechanics. Jung and colleagues compared Prodisc C and Prestige LP (Medtronic Spine, Memphis, TN) using a C3-C6 finite element model under a follower load hybrid loading protocol (1 Nm for the intact model).[30]

The authors found that the center of rotation was 1 mm more posterior for the Prestige LP CDA model under extension, and this could have contributed to 15% less motion and 10% less facet load at the index level. The facet load is likely influenced by the decreased moment arm length with a more posterior center of rotation. Following the same logic, if the center of rotation translates anteriorly, this could create a longer moment arm and subsequently increase the facet load. Lateral translation of the center of rotation may create asymmetrical facet loading. This is an important biomechanical consideration with open unconstrained designs with anteroposterior, lateral and oblique translation of the center of rotation, such as Mobi-C (Zimmer Biomet Spine, Warsaw, IN). Moreover, the shape (sphere versus oval) and location (superior versus inferior endplate) of the ball in a ball-and-socket joint design (like the one found in Prodisc C) can change the biomechanics. An oversized socket could theoretically lead to translation of the socket over the core, blurring the line between constrained and semi-constrained discs despite a fixed center of rotation.[31] These topics need additional studies with military-specific loads, e.g., head supported mass and elevated accelerative loads. They are future research topics.

Cervical Disc Arthroplasty With Bryan

The Bryan disc resulted in less extreme biomechanics compared with the ACDF and Prodisc C options. This may be attributable to its enclosed design that more closely mimics the natural disc segment. It maintains almost identical extension as the intact physiologic model while reducing flexion at the index level. Although it increased the facet force at the index level in extension, it was not as significant as Prodisc C. This may be related to a lack of significant elevation in ROM at the index level with the Bryan disc compared with Prodisc C. In fact, the Bryan disc demonstrated large physiological ROM at both the index and adjacent levels. To our knowledge, there is a lack of human cadaver literature investigating the facet forces at the index level after the Bryan disc arthroplasty. Gandhi and colleagues used a C2-T1 finite element model under hybrid loading (2 Nm for intact spine) to compare the conventional fusion, i.e., anterior cervical arthrodesis, and Bryan and Prestige LP.[32] Bryan increased the flexion-extension ROM at the index level by $\sim 15\%$ compared with $\sim 24\%$ for Prestige LP. The increase in the facet force at the index level under extension for Bryan (34 N) was slightly lower than Prestige LP (36 N). In a more recent modeling study by the same authors, they reported less extreme increases in ROM and facet force at the index level under flexion and extension for Bryan when compared to Prestige LP.[33] Overall, the Bryan disc led to less dramatic biomechanical alterations at the index and adjacent levels compared with ACDF and Prodisc C. This gives the Bryan disc an advantage when considering CDA for patients with facet arthropathy who demand motion preservation. Although the Bryan disc is technically an unconstrained device, its encapsulated design that prevents supra-physiological ROM at the index level appears to be responsible for these unique biomechanical changes at the index and adjacent levels. From these perspectives, it is important to consider the potential status of the other components of the spinal segments before deciding on the type of CDA to be used to alleviate disorders such as neck pain. This field is still evolving even in the civilian domain, and the above results and discussions are applicable to the military patients.

Limitations

First, the current cervical spine finite element model was based on the geometric information of a single individual cervical spine of a healthy subject, and it can only be used to reflect the change trends of the cervical spine biomechanical response under different physiological loads. Because one generic finite element model was used, statistical interpretations were not possible. Future studies will involve parameterization of the current model. Although the follower force application that accounted for the in vivo head weight and head supported mass simulated the role of muscles (commonly used in spine biomechanical models), it cannot fully replace the human musculature that have more complex contributions to the spinal response. Another limitation is that the actual model of the head and head supported mass complex was not incorporated into the model, and assumptions were made for the actual location of the head supported mass (obtained from reported military studies, cited in the introduction). These assumptions may reduce the segmental motion response and influence of the anterior and posterior load-sharing characteristics, i.e., disc pressures and facet loads. Furthermore, we used the same load locations and magnitudes in all simulations in order to be consistent. In addition, we sized and positioned the artificial discs into our finite element models as routinely done for a surgical case (the neurosurgical authors of this article ensured the accuracy of the CDA and conventional fusion models). Different implant positioning and sizing could affect the biomechanical results.[34] The degree of cervical lordosis could also influence the biomechanical outcome, especially with elastomeric devices such as the Bryan disc.[35]

When comparing finite element modeling and human cadaver studies of ACDF and CDA, important differences should be acknowledged. The ACDF segment in a human cadaver specimen will generally move more than the finite element model. The degree of freedom at the ACDF functional spinal unit can be completely constrained in a finite element study. The cadaver specimens are generally tested first to obtain the biomechanics of the uninstrumented state (to serve as a control) and then undergo instrumentation and repeat testing. Specimens would have to undergo testing four times, under intact, ACDF, and CDA (Bryan and Prodisc C) conditions, in order to investigate the biomechanical effects of all surgical interventions. This would lead to increasing degradation of the specimen with possibly falsely elevated measurements of ROM, facet force, and intradiscal pressure metrics. Because of these issues, finite element modeling was used in the present study.

CONCLUSIONS

Recognizing that ROM is a clinical measure of spine stability/performance, CDA demonstrates a more physiological biomechanical response than ACDF, although the exact pattern depends on the implant design. Anterior and posterior column load-sharing patterns were different between the two CDA implants and may affect implant selection based on the anatomical and pathological state at the index and adjacent levels. Currently, selection of ACDF or a specific CDA option is based on experience as standards do not exist. The present study providing data on anterior (intradiscal pressure) and posterior (facet force) column load-sharing will assist the surgeon in surgical decision-making.

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SUPPLEMENTARY MATERIAL

Supplementary material is available at *Military Medicine* online.

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