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Facet joint loading after 1-, 2- and 3-level cervical disc arthroplasty: a comparison of spiked versus keeled baseplates

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ABSTRACT

Background: The purpose of this study was to examine facet contact forces above, below, and at surgical index levels induced by artificial disc implantation and compare the results from spiked versus keeled baseplates comprising the arthroplasty device.

Methods: Human specimens from C2 to C7 were subjected to flexion, extension, and lateral bending prior to, and following random allocation to spiked or keeled cervical arthroplasty at the index (C5-C6), inferior (C6-C7), and superior (C4-C5) levels. Thin film force sensors were inserted unilaterally into the corresponding facets prior to intact testing. Force data was normalized to the minimum forces recorded during each loading mode under each condition, reported as (Max/Min) force ratio and subjected to a 1-way ANOVA with Dunnett's post-hoc tests for comparison to intact specimens.

Results: Under flexion, compared to intact, all levels displayed a significant reduction in force ratio following a 1- and 3-level implantation for the spiked baseplate device. An increase in force ratio was observed at the index level for a 2-level implantation but was mitigated with the completion of a superior device insertion. No statistical differences were noted for keeled devices. In extension, the spiked baseplate device reduced the force ratio for 1- and 2-level implantations. A 3-level insertion did not alter facet force ratios. For the keeled device, no statistical changes were noted. Lateral bending associated with spiked devices resulted in statistically reduced or nonsignificant changes in facet loading ratios. The keeled devices did not display significant changes to facet force ratios.

Conclusions: Implantation of multilevel disc devices can reduce or sustain unaltered facet loading conditions. In general, 3-level arthroplasty statistically reduced or does not increase facet force ratios compared to intact values. The use of spiked versus keel device baseplates is a clinical selection involving anterior/posterior placement and endplate degeneration conditions.

Background

Cervical disc arthroplasty emerged as an alternative to cervical fusion to alleviate issues such as compensatory range of motion at levels adjacent to a fusion, causing adjacent-segment degeneration. The reduced recovery time following cervical arthroplasty allows for more immediate and accelerated rehabilitation [1–3]. The predominant body of literature associated with biomechanical investigations of cervical disc arthroplasty are focused upon improving the biomechanical range of motion associated with the index or adjacent levels [4–6]. A subset of biomechanical investigations highlights the influence of intra-discal pressures and facet forces due to disc arthroplasty [7,8]. Despite the success of disc arthroplasty in restoring spinal motion, complications associated with facet degeneration have been reported [9].

FDA device/drug status: Not approved.

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Studies investigating the effects of disc arthroplasty on facet forces are few. Within these studies, a significant portion are associated with finite element investigations often involving a single spinal model [7,10–12]. Such an approach may be appropriate in comparing relative effects of surgical interventions under controlled and consistent loading conditions. However, there are drawbacks to these computational models. While the generated models are created from a human cadaveric specimen, the resulting data is based on the mechanical response associated with the specific model geometry when coupled with the device under investigation. As well, input parameters such as boundary conditions at the implant/substrate surface interfaces, facet cartilage shear forces and mechanical processes such as possible subsidence are often simplified or maintained static. Biomechanical processes such as muscle restraint under various loading modes are also simplified to achieve model convergence.

In-vitro biomechanical investigations associated with facet loading are few. The paucity of such studies can be attributed to the inherent difficulties in experimental execution. Perhaps the most challenging aspect of elucidating the effects upon facet joint biomechanics rests with the ability to directly measure physical quantities within the joint itself. Successful measurement of facet force has been achieved through thin film sensors inserted within the superior and/or inferior aspects comprising the joint [13,14]. The drawback to such an approach is that the facet joint capsule must be resected to facilitate sensor insertion. An alternative, noninvasive approach has been advocated by Jaumard, et al. However, while the experimental and theoretical pressure displayed comparable profiles, the experimental values were approximately 50% of the predicted theoretical pressure [15]. The authors cited sensor positioning and orientation as elements contributing to variability in recorded data. Geometrical design of the prosthesis, implant height, and endplate positioning play a role not only in the range of motion but also in the associated facet force [16].

The purpose of this investigation was to evaluate the effects of a multilevel disc arthroplasty procedure using identical motion mechanisms but with different implant baseplates on the corresponding facet forces following implantation. Considering the degenerated conditions associated with human cervical specimens, the investigators hypothesized that implantation of a total disc prosthesis at the index level could reduce facet loading due to disc height restoration but could increase facet forces at adjacent levels. Continued implantation at the degenerated inferior and superior levels could mitigate the altered facet loading conditions due to index implantation.

Methods

Two groups of human cervical spines from C2 to C7 were utilized. Group 1 consisted of 7 specimens (1 specimen of the 8 was not useable) with an age range of 56-79 years. These specimens were assigned to the implant with spiked endplates. The second cohort of specimens, Group 2, entailed 8 specimens with an age range of 33-66 years and were allocated to the keeled implant group. All specimens were prepared by removing excess soft tissue and preserving the intervertebral spinous ligaments. Thin film pressure sensors of 0.2 mm in thickness (A201, 111 N. Tekscan Inc, South Boston, MA) were preconditioned to reduce sensor hysteresis by applying 80% of the sensor capacity for 50 cycles with the sensor placed between a 1 cm diameter × 0.8 mm thick neoprene rubber pad to allow for complete sensing area surface contact. Following the preconditioning process, calibration was performed by application of static compression to the sensor while recording the applied load versus the output of the sensor [17].

Sensors were uniquely identified and inserted into one of the randomly selected (but consistent within a specimen), facet joints located at (C4-C5), (C5-C6), and (C6-C7). A similar insertion procedure has been used previously [14]. It involves a superior arthrotomy of the facet joint capsule to insert the sensor. Once positioned, cyanoacrylate adhesive was applied to the external region of the sensor and the facet joint capsule to fix the position of the sensor within the joint, and seal the capsule thereby resulting in a stable orientation of the sensor within a given facet joint for each specimen [14]. The lateral bending phase of biomechanical testing was always performed to load the instrumented facet joint selected.

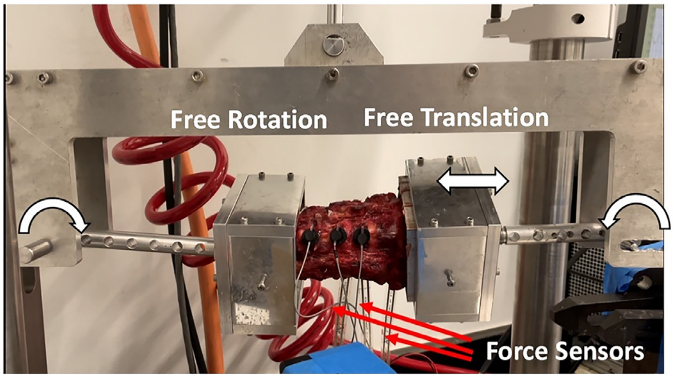

Fig. 1. Test apparatus to apply flexion, extension, and lateral bending. Multiple degrees of freedom permit minimally impeded coupled motion under prescribed loading [18].

The biomechanical evaluation follows a similar previously published methodology [18]. This previous study also included 3-dimensional motion of a spiked disc replacement while monitoring of facet forces. A keeled device was not included in the previous study but is used for comparison in the current study. Though not the topic in this manuscript, the current study also included 3-dimensional motion data for the keeled device under investigation. The facet loading data acquired in the previous study was used for comparison to the keeled disc replacement in the current study. More specifically, under identical loading regimens involving recording of three-dimensional motion and facet forces, the facet data from the previous (spiked implant) was combined with the data from the keeled implant to ascertain facet force differences due to baseplate differences under multilevel implantation.

The specimens were subjected to 20 continuous loading cycles under flexion, extension, and lateral bending at 0.1 Hz thereby allowing for reduction of loading hysteresis during testing [19]. The testing configuration permitted orientation and loading of the specimen without removal from the testing apparatus (Fig. 1) [20,21]. The loading modes were obtained by rotating the specimen into the loading axis of the testing apparatus. Loading was performed in displacement control such that the central vertebra was subjected to a 3 mm displacement as recorded by the actuator of the testing frame (ELF 3300, TA Instruments, New Castle, DE). Using the span distance between supports, this resulted in an angulation of 3 degrees per side for the embedded vertebral bodies in each loading mode [22]. Testing conditions included the intact specimen followed by sequential artificial disc implantations (prodisc Vivo, Group 1 (spikes) or prodisc C, Group 2 (keeled), West Chester, PA) by experienced spine surgeons at the index (C5-C6), inferior (C6-C7), and superior (C4-C5) levels (Fig. 2). All specimens displayed degenerated discs with reduced intervertebral disc height.

Specimens were subjected to the loading regimen under intact conditions followed by implantation of a respective implant at (C5-C6) which served as the index level (Fig. 2). Sizing of all implants for insertion was based upon fluoroscopic imaging and direct visualization by board certified spine surgeons. The surgical technique employed for this study involves extensive uncovertebral joint resection bilaterally in order to decompress the neuro-foramen on both sides, in addition to resection of the posterior longitudinal ligament. This technique was utilized during disc preparation for the current study as well. The testing regimen was applied following subsequent implantations inferiorly at (C6-C7) and again superiorly at (C4-C5) (Fig. 3).

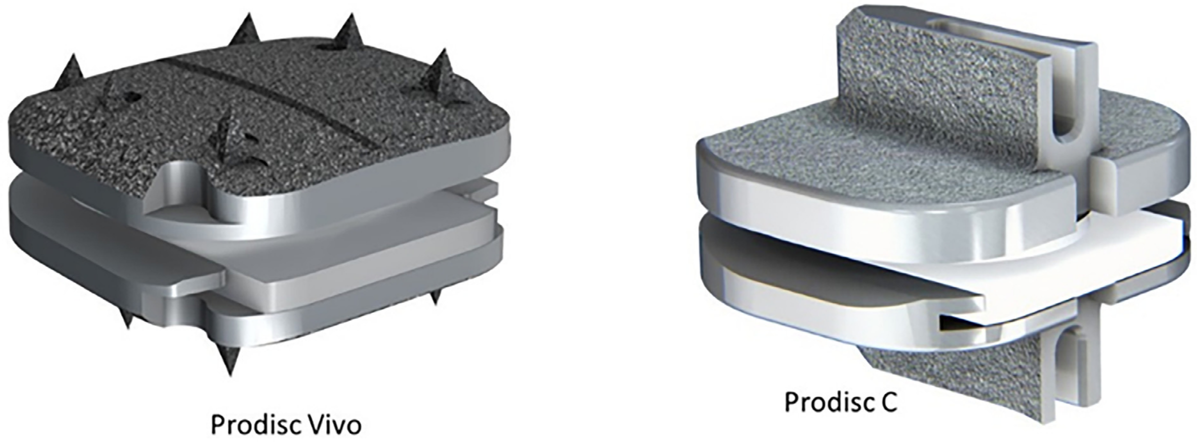

Fig. 2. The prodisc Vivo and prodisc C total artificial cervical disc device [18].

Intact **(C5-C6) Implantation Index** **(C6-C7) Implantation Inferior** **(C4-C5) Implantation Superior**

Fig. 3. Implantation sequence from intact to 3 levels [18].

The output of each sensor versus applied force data was subjected to a linear regression and resulted in specific calibration curves for each sensor. The calibration curve associated with each sensor was used to convert the sensor output voltage to force values in Newtons. For each condition and loading mode, force data was normalized to the minimum force recorded during 20 cycles of loading and reported as the (Max/Min) force ratio. The force data expressed in this format serves to account for the variability of the physiological condition and geometry of the specific facet joint. Use of the absolute maximum force in isolation can lead to excessive loads in cases where facet geometry and configuration generates a baseline "tight" facet joint. Conversely, a "loose" facet joint may result in significantly reduced absolute maximum force values. The force ratio data was subjected to a 1-way ANOVA with Dunnett's post-hoc tests for comparison to intact specimen response (Prism 9.4, GraphPad, San Diego, CA). Significance was set at p<.05.

Results

Spiked Baseplate

In flexion, compared to the intact specimens, the vertebral facet joints at (C4-C5) experienced a statistically reduced force ratios for all implantations (p<.0001, Fig. 4). The index (C5-C6) did not display statistically different facet ratios for 1- and 3-level insertions but manifested a statistically increased facet ratio when an inferior implantation was performed. This elevated facet ratio was mitigated with a superior (C4-C5) insertion and returned a nonsignificant difference compared to the intact leveled. At (C6-C7), the results of flexion produced statistically significant reductions in facet ratios (p<.013) regardless of implantation levels.

Under extension loading, insertion of the spiked total disc replacement resulted in statistically reduced facet ratios at (C4-C5) and (C5-C6) regardless of implantation level (p<.0001, Fig. 5). At (C6-C7), no statistical differences were seen in facet force ratios regardless of surgical level (p>.62). Lateral bending associated with the spiked device resulted in reduced facet ratios at (C4-C5) regardless of implantation level (p<.0001, Fig. 6). At the index level (C5-C6), a similar response was observed with inferior implantation at (C6-C7), where the facet force ratios became increased relative to intact (p<.0001). The 1- and 3-level implantations at the index level resulted in statistically reduced facet ratios relative to intact (p<.0001). The inferior (C6-C7) did not display significant differences relative to intact regardless of implantation levels.

Keeled baseplate

In all loading modes, no statistically significant differences were observed in changes of the facet ratios regardless of implantation level or vertebral location (p>.69, Fig. 7). This is likely because in the case of a keeled insertion, the intervertebral disc space is not distracted to insert the device. Keeled device insertion differs in that a channel is cut into the inferior and superior vertebral bodies, thereby resulting in minimal distraction. In contrast, a spiked baseplate will require disc space distraction to facilitate insertion and positioning of the implant upon the vertebral endplates.

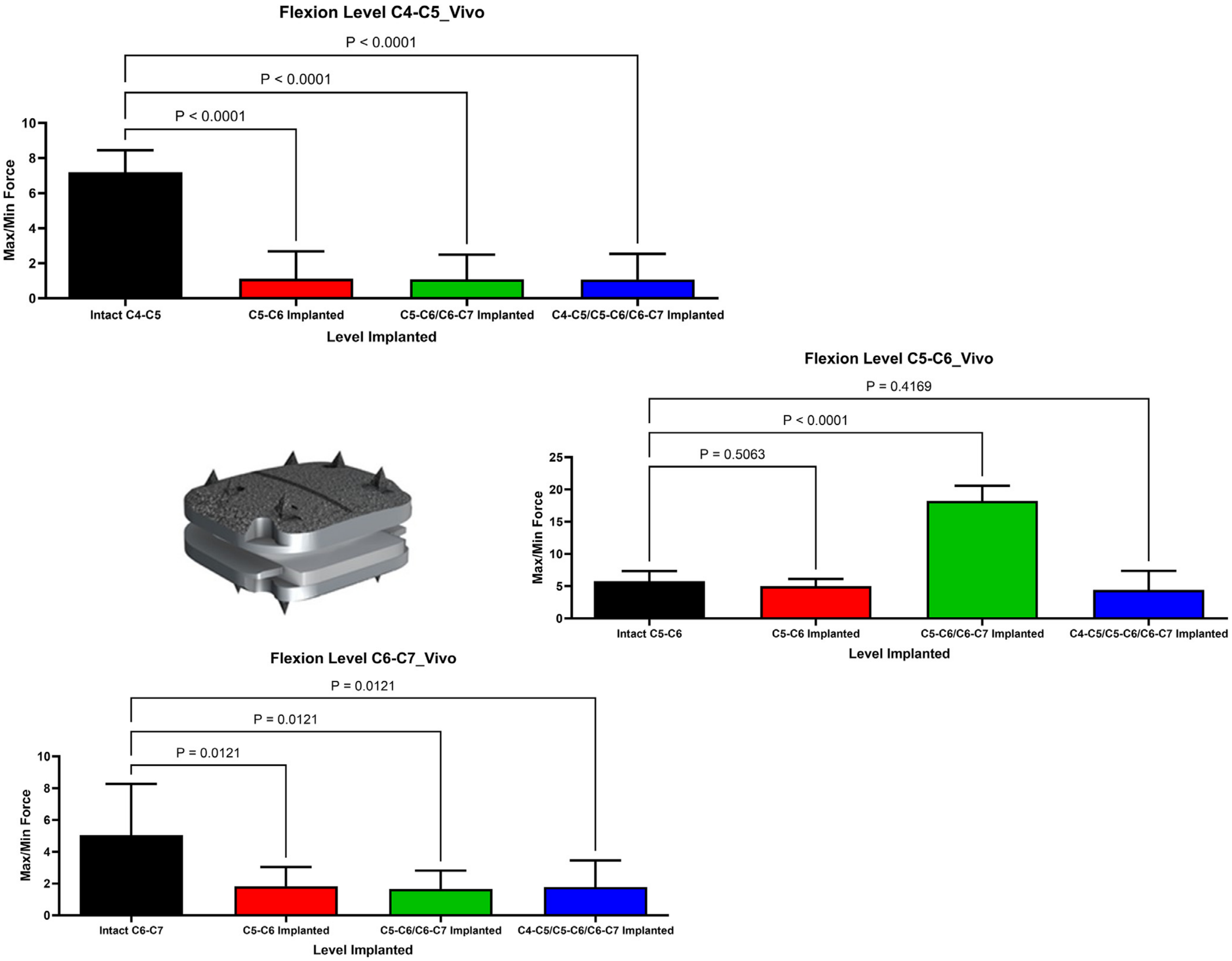

Fig. 4. Flexion results of facet force ratios at the superior (C4-C5), index (C5-C6), and inferior (C6-C7), total disc implantation for the spiked implant.

Discussion

There are numerous studies addressing the mechanical influence of artificial disc insertion upon the facet joint. With the variety of artificial disc designs available, the investigators focused upon studies involving semiconstrained, ball and socket devices with a fixed center of rotation, where possible. While such studies allow for investigation of relative changes due to prosthetic designs and geometries, they are limited by the number of segments modeled, and are often based on healthy patient scans that are degenerated using material properties that do not include the associated geometric changes, nor include effects of distraction on surrounding structures [7,12].

Using a cadaveric based model, Womack, et al., investigated the effects of disc insertion upon range of motion, facet contact forces, and load distribution. prodisc C implant heights of 5, 6, and 7 mm were examined. All disc models involved alteration of the vertebral endplates for congruence and keel insertion. Three sizes of total disc replacements were examined. Provided the implant was appropriately sized, the model predicted values for contact force magnitudes and distribution comparable to those displayed by the intact condition. Furthermore, the contact pressures and load sharing values in adjacent segments were not strongly affected due to the insertion of a total disc replacement at the index level. In addition, insertion of the larger device resulted in reduced facet forces as compared to the appropriately sized implant [10]. Such a result is not unexpected as the insertion of an implant of increased height would distract the posterior elements and result in reduced facet loading.

The effects of total disc replacement were also investigated by Wang, et al., using a Pretec-I device of varying heights (5, 6, and 7 mm) and inter-facet pressure sensors under in-vitro conditions. Implantation of the devices at the (C5-C6) index level resulted in elevated facet joint pressures relative to intact values when 7 mm devices were employed within a disc space height of approximately 5 mm under flexion, extension, and lateral bending. A similar response was noted at the inferior (C6-C7) segment with only loading in flexion demonstrating significant differences at (C4-C5) [16].

In the current study, each disc replacement insertion was sized based upon fluoroscopic imaging. Implant size ranged from 5 to 7 mm in height and included footprints from Medium (12 mm Depth × 15 mm Width) to X-Large (18 mm Depth × 19 mm Width) as determined appropriate for the respective disc space. The results of this study compare well with the finite element work by Womack, et al., and the in-vitro study by Wang, et al., in that when an appropriately sized device is employed, the facet forces at the index and adjacent levels are not significantly different or, are reduced, when compared to the intact condition. In general, lateral bending displayed comparable nonsignificant differences in facet loading compared to the intact specimen during sequential multilevel disc implantation.

The present study included implants 7 mm in height and these devices were deemed appropriate for the respective surgical site and thus

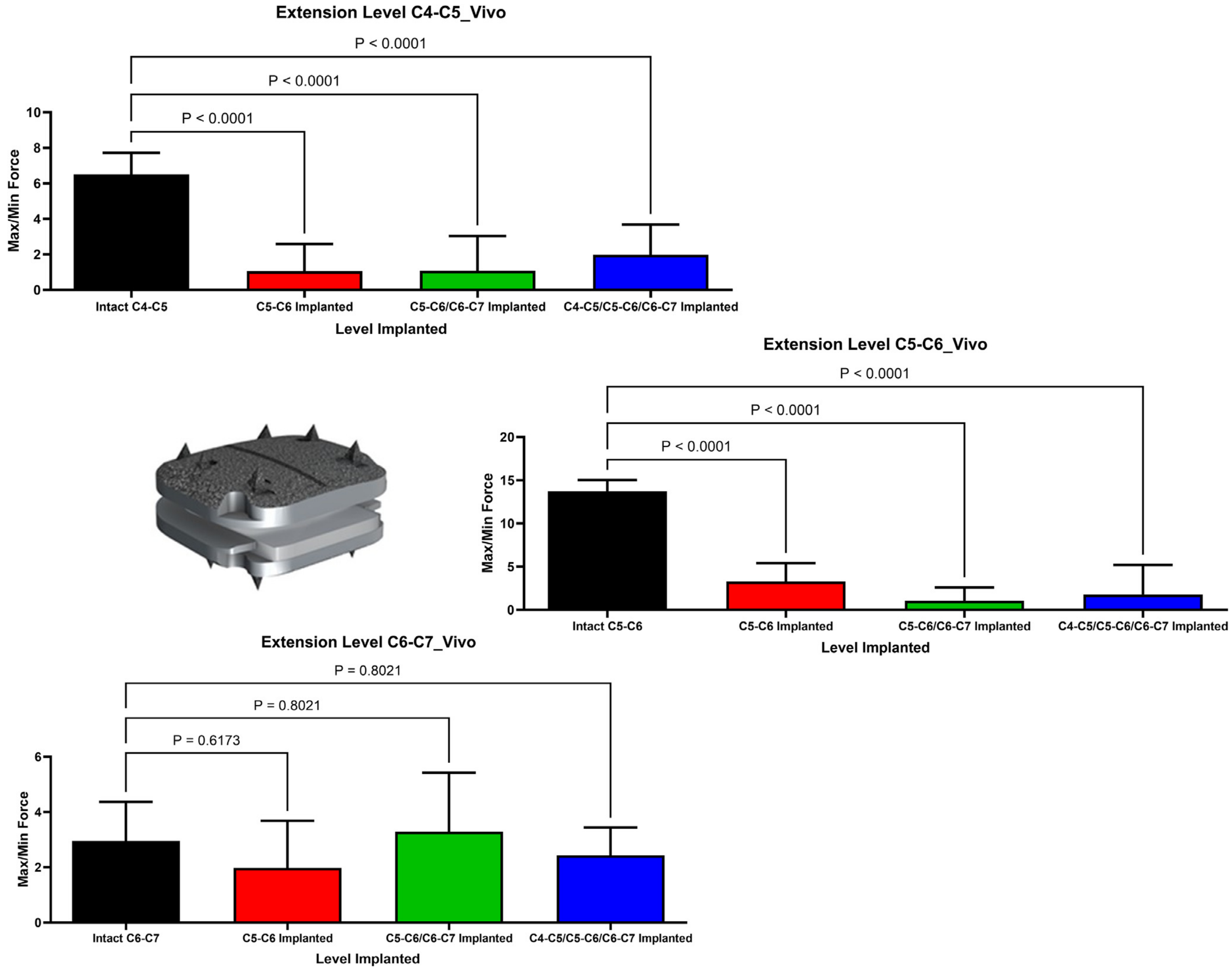

Fig. 5. Extension results of facet force ratios at the superior (C4-C5), index (C5-C6), and inferior (C6-C7), total disc implantation for the spiked implant.

constitute a clinically appropriate implantation resulting in either a reduction or nonstatistical change in the facet force ratio irrespective of the number of implantations or spinal levels implanted. The 1 exception to this statement was the statistically significant increase (p<.0001) at the index level under flexion when a second spiked total disc device was inserted inferior (C6-C7) to (C5-C6). It should be recognized that a third-level implantation of the spiked device superior to the index level at (C4-C5) resulted in mitigating the facet force ratio increase and manifested a return to the intact level (p>.4).

In contrast to these studies and the current study, a finite element investigation by Gandhi, et al., reported considerable increases in facet forces during single- and dual-level implantations of Bryan and Prestige LP implants in a simulated degenerative cervical spine model [11]. The differences in results may be attributable to inputs regarding model material properties to simulate degeneration, boundary conditions, and prosthesis modeling that involved implants of 8 mm in height. The authors reported increased motion at the surgical levels but decreased motion at the adjacent levels regardless of prosthesis or number of implantation levels. A single-level implantation resulted in elevated facet forces at the index level while manifesting decreased facet forces at the adjacent levels. A 2-level disc replacement displayed similar results of increased facet forces at the implanted levels and a reduction of facet forces at the adjacent levels. The implant height of 8 mm could have contributed to increased facet loading at the implantation site due to increased lordosis. In the current study, the size selection was based upon fluoroscopic visualization and evaluated by experienced surgeons to facilitate proper sizing, orientation, and positioning.

An in-vitro study employing facet surface-mounted strain gauges was conducted by Park, et al., in the evaluation of two level prodisc C arthroplasty combined with and without fusion [23]. Though not statistically different, the authors noted that under extension, facet forces were unchanged proximally regardless of configuration, whereas increased facet forces were noted in distal segments except for the disc arthroplasty conditions. Zhao, et al., inserted thin film sensors within the facet joints of (C4-C5), (C5-C6) and (C6-C7) during biomechanical testing of cervical disc arthroplasty at (C5-C6) [13]. The authors did not report a significant difference with respect to facet forces irrespective of the prostheses investigated but reported a significant facet force decrease in the case of simulated fusion. This is somewhat anticipated as the immobilization of the segment after disc height restoration from the insertion of the disc replacement will unload and immobilize the segment.

In the current study, implantation of the devices generally resulted in decreased facet joint loading ratios at the index level with adjacent levels displaying reduced or unaltered facet load ratios. Only under flexion loading, following a previous (C5-C6) arthroplasty, was the subsequent implantation of a disc prosthesis at (C6-C7) result in facet force ratio increase at the index implantation level (p<.0001). Notably, the continued implantation of a prosthesis superiorly at (C4-C5) reduced the (C5-C6) facet force ratio compared to intact values (p<.0001). The increase in facet force ratio in this isolated condition can be attributed to the fact

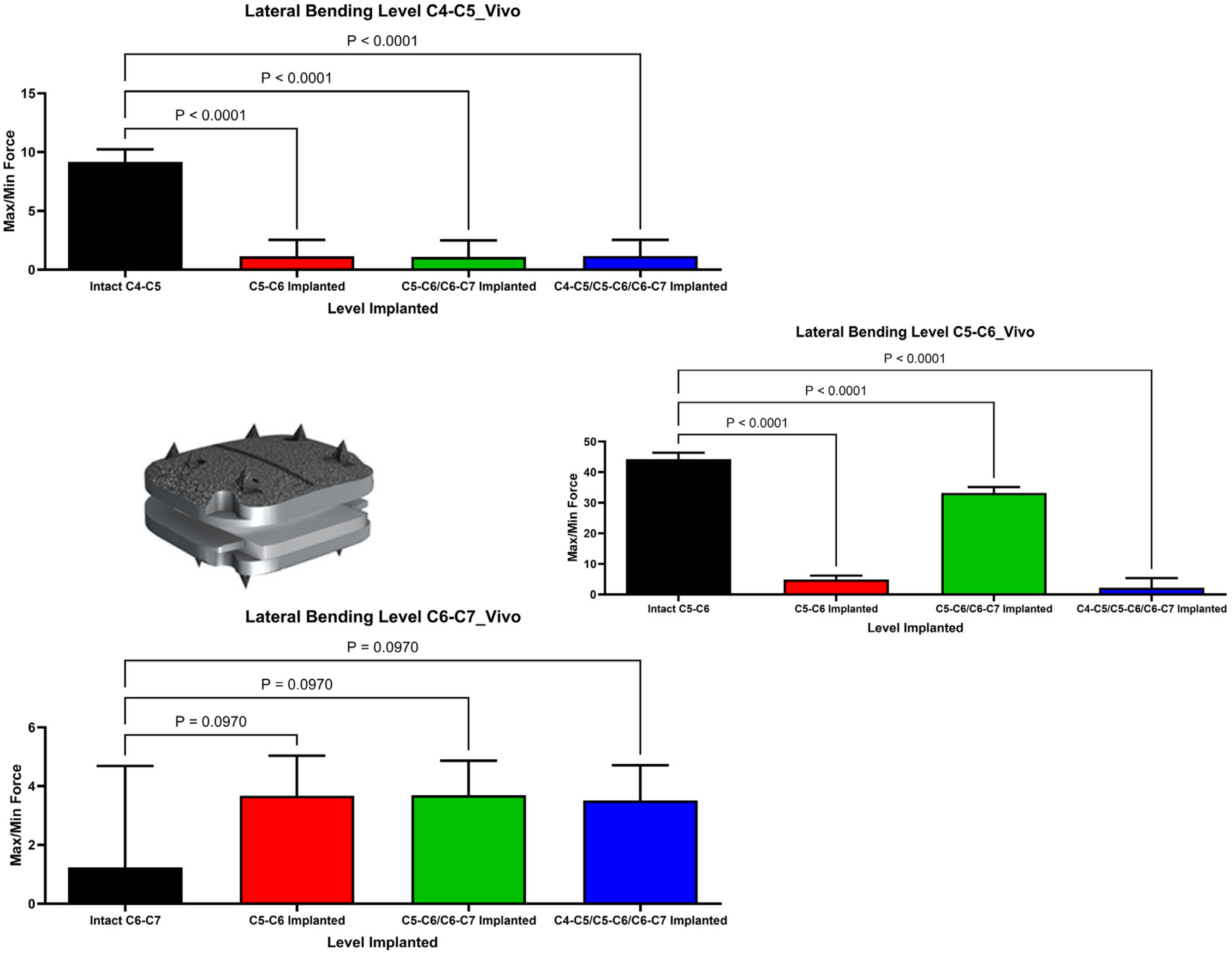

Fig. 6. Lateral bending results of facet force ratios at the superior (C4-C5), index (C5-C6), and inferior (C6-C7), total disc implantation for the spiked implant.

that the computed value contains the minimum force in the denominator. In flexion, the facet joints are predominantly unloaded and thus, use of a small value in the denominator results in a greater force ratio magnitude value. This approach was preferred versus the traditional percentage intact because the second course of applied loading combined with the insertion of any device can alter the specimen response from intact. Thus, the normalization to the minimum force values allows for more clinically relevant deviations to be determined that are reflective of device application and less influenced from previous loading regimens.

It should be recognized that in the previous study involving a similar testing configuration and employing a spiked total disc replacement, the associated motion following multilevel implantation of the devices did not unduly constrain cervical segmental motion in flexion, extension, and lateral bending [18]. Combined with the results from the current study, it appears that multilevel total disc arthroplasty does not unduly alter segmental biomechanics in this in-vitro testing scenario.

The insertion of a pressure probe into the (C5-C6) facet joint by Jaumard, et al., examined the effects of a prodisc C device insertion at (C5-C6) with respect to lateral bending and torsion [24]. The authors reported that under these loading modes no statistically significant differences were observed in the facet forces at the index level, albeit increases under lateral bending were noted. Under lateral bending and torsion, a single level prodisc C implantation was not found to increase facet joint pressure at the index level. While torsion was not conducted in the current study, loading in lateral bending resulted in decreased facet force ratios (p<.0001 for all) at the index and inferior segments when implantation was performed at (C5-C6) and (C6-C7). Superior implantation at (C4-C5) resulted in statistically nonsignificant differences in the facet force ratios at all levels. The use of a pressure probe may artificially elevate facet pressures due to the probe presence. In the current study, the thin film sensors are both thin (0.2 mm) and flexible. Thus, the influence upon the biomechanical response of the facet joint is minimal.

Chang, et al., applied surface strain gauges to infer resultant facet forces [8]. While this process does not disrupt the facet capsule, removal of tissue is required to affix the strain gauge. As well, strain gauge orientation can play a role in data variability between specimens. The uniaxial strain gauge orientation can provide varied response based on the orientation of the underlying substrate strain pattern and the central strain axis of the gauge. Furthermore, the effects of tangential strain may introduce additional variability because of the discrepancy between the substrate strain axis and the gauge axis. In addition. the prolonged testing time may require thermal compensation of the gauge in order not to induce additional strain. The external strain gauge data was not a direct measurement of the facet forces. In the current study, a previously published thin film sensor conditioning and calibration process was used to provide direct internal force data within the facet joint [17]. Permanent attachment of the unilateral sensor position combined with closure of the facet capsule using an adhesive, ensured that the integrity of the

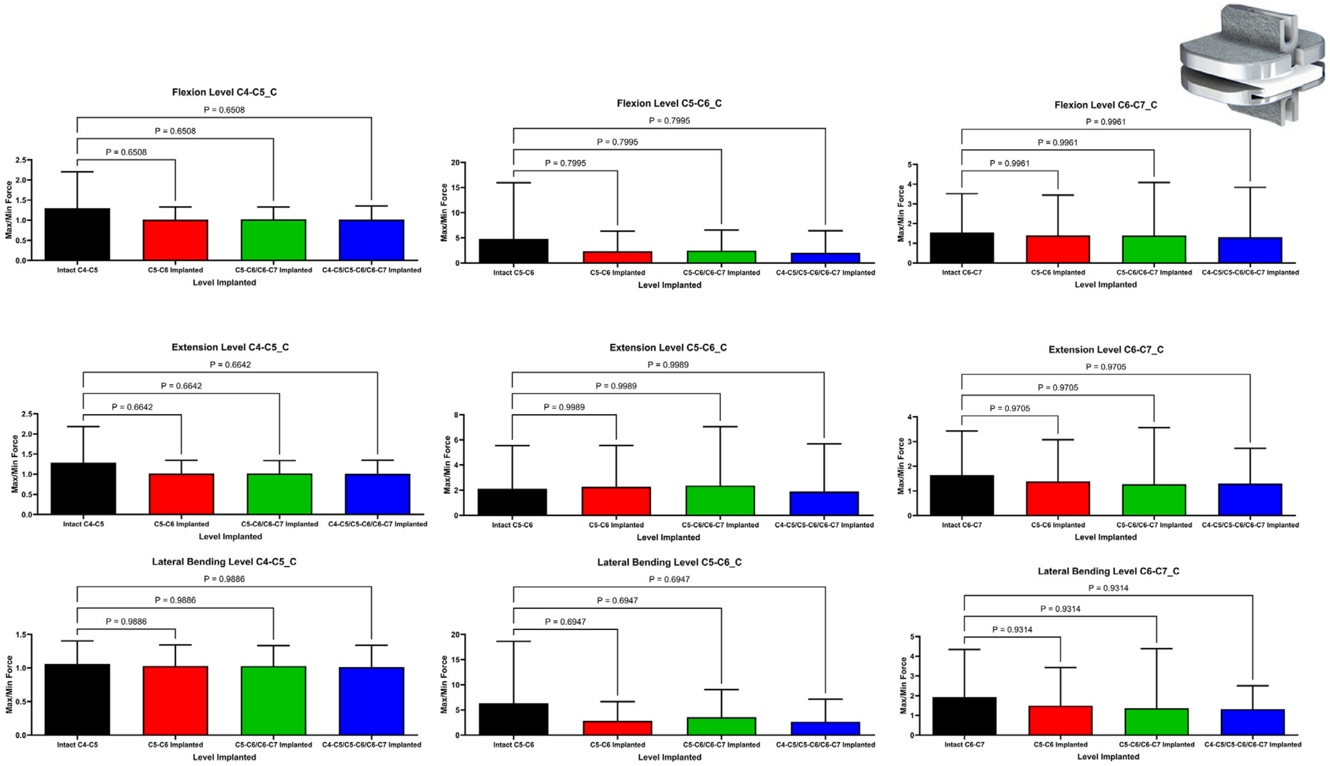

Fig. 7. Results of facet force ratios at the superior (C4-C5), index (C5-C6), and inferior (C6-C7), total disc implantation for the keeled implant for all loading modes.

facet structure and sensor orientation were unchanged from the intact baseline positions [14].

The loading mechanism employed in the current study does not include a follower load. The inclusion of such an element has been advocated to simulate the resultant muscle forces in the spine. Sun, et al., reported the effects of follower loads on the continuous biomechanical response of the subaxial cervical spine [25]. The authors noted that studies typically only examine the endpoints of the loading response and not the continuous profile associated with the response. The results indicate an increase in facet forces and intradiscal pressures resulting from the application of a follower load. More specifically, in the neutral position, the facet forces increase linearly with increasing follower load under extension, lateral bending, and torsion. Under bending or rotation, the center of rotation of the spine segment does not remain fixed and this should be continuously adjusted. Moreover, the follower load magnitude is to be continuously optimized due to the changing applied moment during loading. The authors surmise that unlike the case of the lumbar spine where the facet joint orientation is less variable (82°-86°) as compared to the cervical spine (20°-78°), the compressive forces sustained by the facet joints in the latter increase with follower load magnitude [15,25].

A report involving both in-vitro and computational studies concluded that while a follower load may be applicable in flexion and extension loading, but the effects upon lateral bending and rotation were manifested by increased hysteresis and increased neutral zone [26]. The increase in hysteresis is indicative of the work done or energy required. The loading is applied to consistent moment values with the resulting motion endpoints displaying comparable positions with and without the application of the follower load. The authors depict a dramatic increase in energy to achieve comparable final endpoints. With the excess energy requirements due to the altered dynamic and continuous biomechanical conditions, the propensity for induced pathological complications arises. That is, the dynamic compensatory and physiological compensation afforded via an externally fixed mechanical follower load may not be applicable in the case of the mobile cervical spine involving continuous cyclic motion as was the case in the current study. Crawford, et al., evaluated the effects of adding a follower load to evaluate the facet forces from a disc arthroplasty device and from plating as compared to intact. The authors reported that the inclusion of compressive follower loads did not alter the facet force magnitudes under flexion or extension regardless of condition [27].

The current study presents a testing apparatus that permits loading in flexion, extension, and lateral bending. The loading configuration allows for orientation of the specimen into the prescribed loading plane without disruption of alignment. Though a single functional spinal unit has been evaluated using this apparatus, the current configuration permits multiple spinal segments to be evaluated [20]. The rotating supports in the plane of induced loading and translation plate permit the spinal segment to undergo prescribed loading with minimal constraints to movement. Furthermore, the free rotating specimen sleeves allow for unrestrained rotation. The result is that while undergoing applied loading, the spinal segment can display coupled motion with minimal restriction to induced off-axis loading. The application of comprehensive displacement by the actuator to the rotation arms to generate a 3 mm change in the central vertebra, results in consistent positional motion of the segment endpoints while permitting the inner segments to be minimally constrained while exhibiting specimen specific coupled motion.

This study is one of the few investigations involving in-vitro evaluation of facet loading due to sequential multilevel cervical disc implantation. The use of a minimally constraining testing apparatus permitting specimen specific coupled motion and intrafacet fixed positioned thin film sensors, has resulted in the reduction or nonsignificant change of facet force ratios under sequent multilevel implantations of a prodisc C (Vivo) device. The isolated case of facet force increases in flexion at the index level following inferior implantation displayed statistically reduced facet force ratios with the insertion of a device superior to the index surgery. The testing regimen and use of cyclic preconditioning for thin film sensors provides a convenient and efficient methodology for facet force determination by employing the minimum facet force as the normalizing parameter.

The use of 2 cervical arthroplasty devices differing only in device baseplates permitted a direct evaluation of how facet forces may be influenced through distraction to place a properly sized intervertebral motion sparring device. In both cases, the resulting facet force ratios were, for the most part, reduced or were statistically unchanged relative to the intact conditions. The older age range of the Group 1 (spiked) specimens may have been more susceptible to disc space height reduction and thus, prosthesis insertion likely increased the disc space gap and resulted in decreased facet force ratios. The keeled version of the arthroplasty device retained the facet force ratios comparable to the intact condition as increased distraction for insertion is not required since a channel for implant insertion is placed in the inferior and superior vertebral bodies.

Clinically, this current study provides a biomechanical basis for multilevel total disc arthroplasty. Implantation of motion sparing devices can improve mobility, evidence of altered biomechanics at adjacent levels have been reported. It should be recognized that the application of these devices should be performed by experienced surgeons, where optimal positioning and sizing is more likely to be realized. Under these conditions, the current study indicates that facet loading is reduced or remains unaltered. As with all computational and experimental studies, the current investigation study is limited by use of mechanical testing protocols where, yet unknown true values related to muscle activation and response to loading can be prescribed. As with all biomechanical studies, reproducible testing protocols employing clinical experts can yield meaningful guidance regarding clinical outcomes. Through an iterative process, verification of biomechanical studies can be ascertained via clinical studies, which in turn provides a basis for further biomechanical work to explain clinical findings.

Conclusions

Based on this number of specimens, implantation of the prodisc devices up to three levels can, in general, reduce or retain facet force ratios so as not to overload the intact specimen. Regarding the initial hypothesis considering the possibility of mitigated compensatory facet forces due to additional insertions was also verified as exhibited by a reduction or nonsignificant change in facet forces. Future studies involving adjustment of the anterior/posterior placement in multilevel disc arthroplasty may be required to fully understand the potential alterations in facet loading to the presence of multiple devices.

Declaration of competing interests

One or more of the authors declare financial or professional relationships on ICMJE-NASSJ disclosure forms.

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