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# MULTIDIRECTIONAL FLEXIBILITY ANALYSIS OF CERVICAL ARTIFICIAL DISC RECONSTRUCTION:

## *IN VITRO HUMAN CADAVERIC SPINE MODEL*

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Running Head: Multidirectional flexibility of cervical disc replacement

**Abstract**

    **Object.** The in vitro experimental study was conducted to investigate the initial biomechanical effect of artificial intervertebral disc replacement in the cervical spine. The multidirectional flexibility of replaced and adjacent spinal segment was analyzed using a cadaveric cervical spine model.

**Methods.** Using seven human cadaveric occipitocervical spines, the following three cervical reconstructions were sequentially performed at C5-6 level after anterior diskectomy: Anterior artificial disc replacement with bioactive three-dimensional fabric disc (3-DF disc: 3DF); Anterior iliac bone graft (AG); and Anterior plate fixation with iliac bone graft (AP). Six unconstrained pure moments were applied with a six-degree-of-freedom spine simulator (6DOF-SS) and three-dimensional segmental motions at the operative and adjacent segments were measured with an optoelectronic motion measurement system. The 3DF group demonstrated statistically equivalent range of motions (ROMs) when compared to intact values in axial rotation and lateral bending. The 45% increase of flexion-extension ROM was demonstrated in 3DF group; however, neutral zone analysis did not reach a statistical significance between intact spine and 3DF. AG and AP reconstructions demonstrated statistically lower ROMs when compared to 3DF in all loading modes (P<0.05). The adjacent level ROMs of 3DF group demonstrated nearly physiological characteristics at upper and lower adjacent levels. The excellent stability at the interface maintained during a

whole testing without any device displacement and dislodgement.

**Conclusions.** The stand-alone cervical 3DF disc demonstrated nearly physiological biomechanical characteristics at both operative and adjacent spinal segments in vitro, suggesting an excellent clinical potential for cervical artificial disc replacement.

Key words: Artificial intervertebral disc, Cervical spine, Biomechanics

**Introduction**

The recent artificial disc technology has rapidly advanced and provided a great potential for changing treatment strategies of several spinal disorders.[2,3,5,6,8,12,13,16,17,19,20-26,39,40,44] Specifically, in the cervical spine, the great attention has been focused on the adjacent segment disease after anterior and posterior arthrodesis.[18,31] Although patients who present with neural compressive lesions causing radiculopathy or myelopathy often require anterior decompressive surgeries, the anterior arthrodesis has been generally an unavoidable procedure following a neural decompression. Hilibrand et al. reported 374 patients having 409 anterior cervical arthrodesis followed for up to 21 years after Smith-Robinson anterior cervical fusion.[18] They found symptomatic adjacent segment disease occurring at a relatively constant incidence of 2.9% per year (range: 0-4.8% per year). Although this adjacent segment disease could not be exactly differentiated from progressive spondylotic change due to natural history, survivorship analysis projected that 25.6% of the patients (95% confidence interval: 20-32%) who had an anterior cervical arthrodesis would have new disease at an adjacent level within 10 years after operation. As an alternative to arthrodesis, an artificial disc serves to replace the symptomatic disc, restores the functional mobility and disc height of the motion segment, and protects neurovascular structures.

The authors' artificial intervertebral disc is based on the concept of a durable and biomimetic design with surface modification that enables a biologic bonding to the vertebral

body. It substantially consists of a triaxial three-dimensional polymer fabric (3-DF) woven by an ultra-high molecular weight polyethylene (UHMWPE) fiber, and spray-coated bioactive ceramics on the disc surface.[20,24,34,35,38] The previous studies have demonstrated that its biocompatibility, endurance, and biomechanical property were similar to those of the normal disc. [20,24,34,35,38] The in vivo study using a sheep model demonstrated the excellent interface bonding and preservation of segmental spinal mobility up to two years period.[23,24,38]

Although there are some cervical artificial discs reported and investigated in clinical trials, only a few in vitro studies have been conducted in terms of biomechanical properties of replaced spinal segments with cervical artificial disc.[25,43] There is still a paucity of information regarding multidirectional flexibility changes of artificial intervertebral disc replacement when compared to intact spine and other conventional spinal reconstruction procedures. Specifically, the device design of constrained, unconstrained, or biomimetic and surgical technique influence the local and global biomechanics of replaced cervical spines.

To investigate the initial biomechanical effect of artificial intervertebral disc replacement in the cervical spine, the multidirectional flexibility of replaced and adjacent spinal segment were analyzed using a cadaveric cervical spine model.

**MATERIALS AND METHODS**

*Design and biomechanical properties of artificial intervertebral disc (3-DF disc)*

The triaxial three-dimensional fabric disc was a semi-elliptically shaped near-net woven with an ultra-high molecular weight polyethylene (UHMWPE) fiber bundle, which was coated by linear low density polyethylene.[20,23,24,34,35,38] (Figure 1) The 3-DF disc consisted of a number of fibers in the x-, y-, and z-axes and their respective multilayers with some alignment ratios in three dimensions. To enhance an initial stability to vertebral endplate, two ultra-strength bioresorbable pins made of hydroxyapatite/poly-l-lactide composite (HA/PLLA) were placed near the center of the prosthesis.[36,37] The bioactive ceramics granules were spray-coated to the designed depth with particulate unsintered hydroxyapatite (u-HA).

Several human 3-DF prototypes were woven with orthogonal or off-angle fiber alignment and received cyclic tensile-compressive and torsional tests. And finally, the off-angle 45 degree model was selected based on a superior torsional property to the orthogonal and off-angle 30 degree models.[20,23,24,34,35,38] The arrangement of layer numbers and alignment ratio among three weaving axes resulted in balanced mechanical properties.

*Specimen Preparation*

A total of seven fresh-frozen human cadaveric occipitocervical spines (Occipital -T2) were harvested en-bloc and utilized in this investigation. The specimens were immediately

packaged in double-thickness plastic bags and stored -20 Celsius. Prior to biomechanical

analysis, standard anteroposterior and lateral plain films were obtained to exclude specimens

demonstrating intervertebral disc or osseous pathology. In preparation for biomechanical

testing, the specimens were thawed to room temperature and cleaned of all residual

musculature, with care taken to preserve all ligamentous attachments and facet joint capsules.

The proximal (C1-2) and distal (T1-2) ends of the specimen were secured in rectangular

metal containers using eight compression screws and cross-fixed Steinmann pins,

respectively, for fixation.   Four Plexiglas motion detection flags were then placed on the

anterior aspects of C4 to C7 vertebral bodies. Each flag was equipped with three

non-co-linear light emitting diodes designed for detection by an optoelectronic motion

measurement system (3020 Optotrak System, Northern Digital Inc., Waterloo, Ontario).

### *Three-Dimensional Flexibility Testing*

Testing was performed using a custom designed six-degree-of-freedom spine simulator

(6DOF-SS) configured with an Optotrak 3020 motion analysis system (Northern Digital Inc.,

Waterloo, Ontario). The 6DOF-SS apparatus is configured with three independent stepper

motors, harmonic drives and electromagnetic clutches, which are capable of applying pure,

unconstrained rotational moments (±) about three axes - X, Y and Z.   Unconstrained

translations (±) were permitted using linear bearing guide rails (X and Z) and MTS actuator

(Y axis) (Figure 2). To determine the multidirectional flexibility, non-destructive,

unconstrained loading parameters included six pure moments - flexion and extension (± X axis), lateral bending (± Z axis) and axial rotation (± Y axis) applied to the superior end of the vertically oriented specimen while the caudal portion of the specimen remained fixed to a testing platform. A maximum applied moment of ± 2 Nm was used for each loading mode and applied at a stepper motor rate of three degrees/second. A total of three load / unload cycles was performed for each motion with data analysis based on the final cycle. For the six main motions - corresponding to the moments applied - the operative and adjacent level vertebral rotations (degrees) were quantified in terms of peak range of motion (ROM) and neutral zone (NZ). ROM is defined as the peak displacement from the initial neutral position to maximum load, while NZ represents the motion from the initial neutral position to the unloaded position at the beginning of the third cycle.[29] To prevent desiccation during assessment, specimens will be moistened with 0.9% NaCl sterile irrigation solution.

*Surgical Reconstruction Groups*

Following analysis of the intact spine, a complete diskectomy was performed at the C5-C6 level to permit implantation of the 3-DF Device (Figure 3A). The complete removal of the cartilaginous endplates as well as exposure of posterior longitudinal ligament allowed the appropriate placement of 3-DF device. The cervical 3-DF device was 18 x 15 x 7mm in width, A-P length, and height, respectively. Using a specially designed distracter and disc inserter, 3-DF disc was inserted into disc space under adequate distraction force while

protecting two bioresorbable pins. After tapping the device into the final placement position, the distraction force was released and bioresorbable pins strongly held both endplates (Figure 3B,3C). Following 3-DF Device testing, the C5-C6 level was subsequently reconstructed using a tricortical autologous graft from an iliac crest (Figure 3D). The graft height was strictly sized to fit the diskectomy gap under the sufficient distraction force. Following the anterior iliac bone graft testing, anterior plate system (Atlantis anterior plate system; Medtronic Sofamor Danek, Memphis, TN) was placed according to manufacturers' surgical standard (Figure 3E). Importantly, biomechanical testing of the destabilization defect was not performed, as this may disrupt the remaining annulus and facet capsule integrity.

## *Data and Statistical Analysis*

The intervertebral range of motion (ROM) at the operative C5-6 level was calculated as the sum of the neutral and elastic zones (NZ+EZ = ROM) and represented the peak total range of motion (Euler angles rotation) at the third loading cycle. The expressed degrees of rotation (axial rotation ± Y-axis; flexion-extension ± X-axis and lateral bending ± Z-axis) for multi-directional flexibility analyses are according to the three-dimensional conceptual framework of Panjabi.[28] The non-destructive range of motion data was normalized to the intact spine condition for each loading mode. Neutral zone was also expressed by normalized percent to the intact spine value. Statistical analysis included descriptives and a One-way

Analysis of Variance with Student-Newman-Keuls test for group-to-group comparisons.

Comparisons with values of p<0.05 were considered statistically significant.

**RESULTS**

*Operative level ROM analysis*

In axial rotation, intact spine and three surgical reconstruction groups formed statistically different subsets (F=6.16, P=0.003). The reconstruction with 3DF disc demonstrated statistically equivalent rotational motion of 123% compared to the intact condition (Figure 4). However, the addition of autograft (71.4±36%), and anterior plate (59.5±33%) all significantly reduced motion compared to the 3DF disc construct (p<0.05). In flexion-extension, 3-DF disc increased overall flexion-extension motion to 145.2±41.6% compared to the intact condition (p<0.05). The addition of autograft (46.6±32.4%) and anterior plate (16.8±10.9%) significantly reduced flexion-extension ROM compared to the 3-DF disc construct (p<0.05). Reconstruction with the 3DF disc demonstrated statistically equivalent lateral bending ROM to 111.5±15% compared to the intact condition. The addition of autograft (48.2±26.9%), and anterior plate (56.55±31.8%) markedly reduced the motion compared to the 3-DF disc construct (P<0.05)

*Operative level NZ analysis*

The neutral zone at the operative level demonstrated a same trend with the operative ROM data (Figure 5). In all three loading modes, the NZ of 3-DF disc group was statistically equivalent to that of intact spine. However, the NZ of autograft and anterior plate groups

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demonstrated significantly lower values than those of intact spine and 3-DF disc in flexion-extension (P<0.05). In lateral bending, the autograft significantly reduced the NZ when compared to the intact spine (P<0.05).

*Adjacent level ROM analysis*

The upper adjacent segment ROMs at C4/5 level were statistically equivalent among intact spine and three surgical groups in axial rotation and flexion-extension (Figure 6). In lateral bending, reconstruction with 3-DF disc, anterior autograft, and anterior plate demonstrated significantly larger ROM values that that of intact spine (P<0.05)

The lower adjacent segment ROMs at C6/7 level were statistically equivalent between intact and three surgical reconstructions in all loading modes (Figure 7).

Following all biomechanical testing, 3-DF device did not show any device loosening or dislodgement. The initial stability afforded by an effective disc height and two bioresorbable pins maintained after several cycles of testing.

**Discussion**

To date, several cervical artificial discs have been reported with different device designs and concepts, however, basic biomechanical works with scientific prudence have been scarcely reported.[7,14,33,43] Recent artificial disc designs were classified into a metal on polymer composite, [4,14] metal on metal design,[7] and exclusive polymer fabric.[20,23,24,38] Goffin et al. reported preliminary clinical cases of 60 patients with Bryan cervical disc prosthesis up to one year.[14] The device consisted of a polyurethane nucleus designed to fit between two titanium plates with a sterile saline lubricant. This disc was designed as a constrained type in contrast to unconstrained type of lumbar SB Charite disc.[26] The range of motion at one year averaged at $9 +/- 6$ degrees with acceptable pain reduction and neurologic recovery. Cummins et al. reported an artificial metal joint allowing a screw fixation to the consecutive two vertebral bodies and segmental spinal motion at the joint placed in the original disc space.[7] The report did not demonstrate the quantitative segmental motion preserved and the metal-related complications of screw pullouts, broken screws and subluxation of the device were presented.[7] The transient hemiparesis and dysphagia were reported clinical symptoms. In hip joints, the metal on metal joint mechanism was reported to cause an early loosening of the device, and modified to polyethylene back mechanism allowing shock absorption and stress relaxation.[9,32] This concern was also pointed out in lumbar metal on metal prosthesis by Ooij et al., demonstrating complications of SB Charite disc in twenty-seven cases.[27]

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There are several advantages of 3-DF disc in the cervical disc replacement. The 3-DF disc consists of a monofilament involving multi UHMWPE fibers, which allows the arrangement of textile density and fiber alignment.[23,24,34,35] Its dynamic mechanical mobility is biomimetically controlled to the values nearly equivalent to the natural disc.[34,35] The construction with soft organic materials will prevent surrounding soft tissue damages when it dislodges as well as a relative easiness of revision surgery. Ooij et al. reported series of twenty-seven patients with SB Charite disc in the lumbar spine, presenting several complications. [27] The reported complications were subsidence of the prosthesis, anterior subluxation of polyethylene core, polyethylene wear and compression of great vessels, requiring revision surgeries. This type of modular unconstrained disc design can cause the failure between components as well as wear debris production. The biomimetic and biocompatible 3-DF disc has fewer possibilities to cause these problems.

The present study investigated initial multidirectional flexibility of artificial intervertebral disc replacement using a cadaveric cervical spine model. Although several cervical artificial discs have been reported,[4,7,14,25] there have been few reports investigating biomechanical characteristics of these devices.[25,43] The range of motion with 3-DF disc was statistically equivalent to that of intact spine segment in axial rotation and lateral bending; however, it showed the high value of 145% in flexion-extension loading. McAfee et al. reported the segmental biomechanics of two types of PCM disc using a same experimental

set-up at C5-6 level.[25] The axial rotational ROMs of low profile PCM and fixed PCM discs were approximately 130% to the intact value without a statistical difference from intact. Cervical 3-DF disc demonstrated 122% of axial rotational ROM to the intact and this was regarded as a physiological mobility when additionally considering equivalent NZ value to the intact. In turn, PCM discs demonstrated relatively limited flexion-extension ROM of approximately 85 to 95% to the intact segment, although PCM disc has an unconstrained nature of design typically allowing the hypermobility of reconstructed segment. This initial hypermobility of unconstrained artificial disc was already demonstrated in the lumbar SB Charite disc using a cadaveric spine model by Cunningham et al.[8] Cervical 3-DF disc demonstrated 45% increase of flexion-extension ROM and its long-term effect on operative level degeneration and adjacent disc level was unknown. However, when we calculated the absolute rotational angle, the angle was 14 degrees that was considered within the normal range reported by White, et al. and Dvorak, et al..[10,11,41]

Previous in vivo animal and clinical studies demonstrated that the replaced spinal segment with artificial disc tended to be stiffer in the living tissue with time.[15,23,24,25,30] The multicenter clinical trials of Bryan cervical disc prosthesis also demonstrated a tendency of immobilization, while the average range of flexion and extension was retained at nine degrees (1 to 21 degrees).[15] The appropriate initial mobility of cervical artificial disc is still unknown, however, it differs between constrained, unconstrained, and biomimetic device

designs. When considering a basic device design of biomimetic structure of 3-DF disc, the initial mobility can be set at the relative hypermobility and it may be approaching to the normal mobility in a long-term period. The control of in vivo motion preservation is the future problem to be solved in this field.

Adjacent segment biomechanics is another matter of concern in artificial intervertebral disc reconstruction. The lower adjacent segment ROM of 3-DF disc was statistically equivalent to that of intact segment in all loading modes. The upper adjacent segment ROM of 3-DF disc was statistically equivalent to the intact segment in both axial rotation and flexion-extension loadings, however, in lateral bending, statistically higher ROM values were detected in 3-DF, autograft, and autograft combined with anterior plate reconstruction when compared to intact segment. This adjacent segment response in autograft and anterior plate groups was explained by the operative level increase of lateral bending stiffness in these groups, however, the change in 3-DF segment was inexplicable. There has been only one report by Wigfield et al. demonstrating an adjacent segment biomechanics after the artificial metal joint replacement of Bristol prosthesis.[43] In this study, the internal stress distribution at the adjacent segment was investigated between spinal fusion and artificial joint replacement in the cadaveric spine model. They clearly demonstrated the decrease of anteriorly situated stress peak at upper adjacent level in artificial joint replacement when compared to spinal fusion. The present study showed that the

physiological adjacent segment mobility was preserved in most of spinal loading modes except a lateral bending.

The cervical artificial intervertebral disc has a great potential for extending the frontiers of cervical spine surgery. Although single or two-level cervical lesion with myelopathy or radiculopathy has been often treated via anterior approach, this has necessitated the anterior spinal fusion with bone graft. Anterior artificial disc replacement will preserve the segmental spinal mobility and a disc height even following the neural decompression. However, there are still unsolved problems in multiple and contiguous use of artificial discs, the physical endurance of the device at adjacent disc pathology to the multiple-level arthrodesis, and revision strategies. The artificial disc replacement surgery has a great possibility to change the biomechanical property of functional spinal unit and instantaneous axis of rotation at the operative segment, therefore, its inherent biomechanics as well as segmental property in cadaveric spine model should be carefully examined in vitro. Multiple-level disc replacements have a chance to change the cervical spine mechanics extensively as well as decreasing the chance of interface bone ingrowth. The use of artificial disc at the adjacent segment pathology to multiple segment arthrodesis will dramatically increase the mechanical stress to the artificial disc; therefore requires the sufficient durability with physical dynamic mobility. The 3-DF disc did not cause the wear debris after 63 million alternating stresses for anti-fatigue testing, which were equivalent to natural biological

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movements for a period of more than 30 years. [35] There have been no experimental study

reported in terms of high cycle stress testing except Shikinami, et al. An in vivo goat study

by Anderson et al. demonstrated the polarizable foreign material and partially polarizable

intracellular granular material exterior to the dura mater and in macrophages at periprosthetic

tissues with Bryan cervical disc replacement.[1] The significance of this wear debris cannot be

determined unless cytokines are specially looked for, however, the metal on polyethylene

type prosthesis has a tendency to cause wear complications as shown in general joint

arthroplasty.[27] Ooij et al. reported complications of lumbar artificial disc replacement in

twenty-seven patients with the SB Charite disc prosthesis, highlighting recent problems of

metal on polyethylene type prosthesis.[27] Most frequent failures reported were a subsidence

of the device, migration, progression of facet arthrosis and polyethylene wear, requiring

salvage spinal reconstruction surgeries. One case in this series also required the removal of

the device due to anterior dislocation with compression of great vessels. There have been a

few clinical reports regarding a cervical artificial disc replacement, demonstrating two major

issues of device failures and spontaneous segmental fusion.[7,14,30,33,42] Pointillart, et al.

described a hemiarticular type disc prosthesis and encountered circumferential spontaneous

fusion in eight of ten patients.[30] Cummins et al. reported the artificial metal joint prosthesis

and described a significant number of complications such as screw pullouts, broken screws,

transient hemiparesis due to drill injury, and persistent dysphagia.[7] Considering these

complications, the cervical artificial disc should have a low profile design, superior initial

stability that holds both endplates, and materials that are less vulnerable to surrounding

important structures. The revision surgery of metal on metal, or metal on polyethylene type

prosthesis requires the huge amount of bone resection as well as the significant technical

difficulty and neurologic risk. The present prosthesis possesses above three benefits and

facilitates the revision surgery with simple excavation of the material. To assure in vivo

biological and long-term effectiveness of 3-DF disc, we are conducting a baboon study

before starting a clinical implantation.

**Conclusions**

To investigate the initial biomechanical effect of artificial intervertebral disc replacement

in the cervical spine, the multidirectional flexibility of replaced and adjacent spinal segment

was analyzed using a cadaveric cervical spine model. The stand-alone cervical 3-DF disc

demonstrated nearly physiological biomechanical characteristics at both operative and

adjacent spinal segments in vitro, suggesting an excellent clinical potential for cervical

artificial disc replacement.

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Figure Legend

Figure 1(1A, 1B): Triaxial three-dimensional fabric disc (3-DF disc)

1A: Bioactive 3-DF disc woven by ultra-high molecular weight polyethylene (UHMWPE) fiber. Two ultrahigh-strength bioresorbable pins (Arrow) made of hydroxyapatite/poly-l-lactide composite (HA/PLLA) penetrated the fabric near the center of prosthesis, projecting both upper and lower side of the fabric with 1 mm length each. The bioactive ceramics granules were spray-coated to the designed depth with particulate unsintered hydroxyapatite (u-HA).

1B: The fiber axis direction was arranged to 45 degrees on the lateral surface of 3-DF disc to achieve the human disc anisotropy.


Figure 2: Oblique view of six-degree-of-freedom spine simulator (6DOF-SS) attached to the specimen. The gimbal is configured with three independent stepper motors, harmonic drives and electromagnetic clutches, which are capable of applying pure, unconstrained rotational moments about three axes- X, Y, and Z. Unconstrained translations are permitted using linear bearing guide rails (X and Z) and MTS actuator (Y axis).


Figure 3 (3A, 3B, 3C, 3D, 3E): Surgical reconstruction groups

3A: Complete diskectomy was performed at C5-6 level. The bony endplate and uncovertebral joints were exposed as well as the preservation of posterior longitudinal

ligament (PLL).

3B: Specially designed device inserter applied segmental distraction. The 3DF disc was inserted while protecting bioresorbable pins, and they held both endplates after the release of segmental distraction.

3C: 3DF disc in place. Device perfectly fitted between bilateral uncovertebral joints.
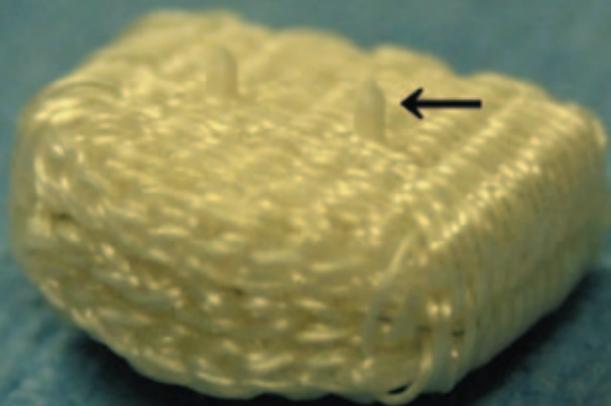
3D: Tricortical autologous iliac bone graft

3E: Anterior cervical plate fixation (Atlantis) with tricortical iliac bone graft
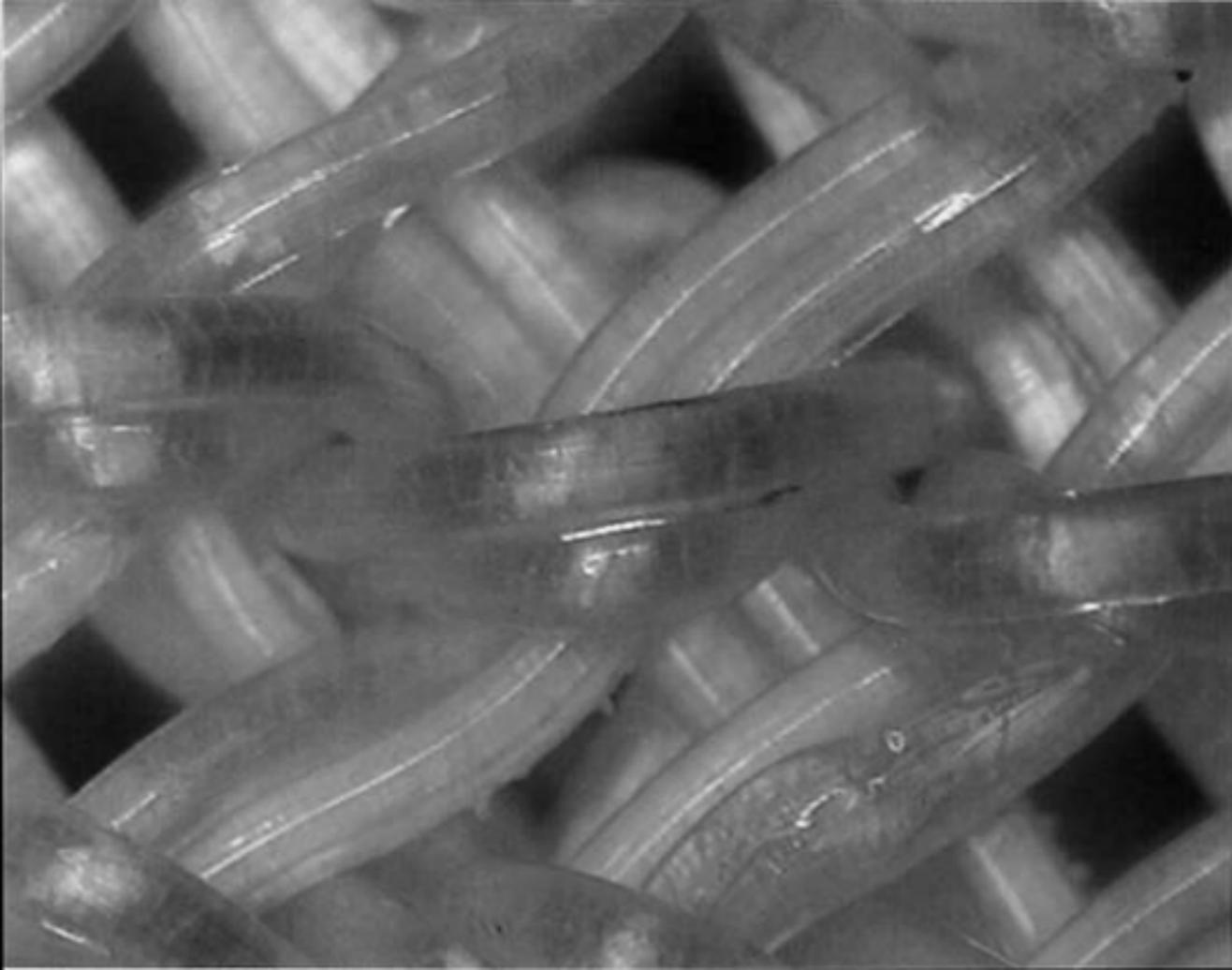
Figure 4: Operative level ROMs of anterior cervical reconstructions under axial rotation, flexion-extension, and lateral bending. Intact: intact C5-6 spinal segment; 3DF: 3-DF disc; Autograft: Autologous iliac bone graft; Auto+Plate: Anterior cervical plate fixation (Atlantis) with tricortical iliac bone graft. * -indicates a statistically significant difference from 3DF. # -indicates statistically significant difference from all other groups.
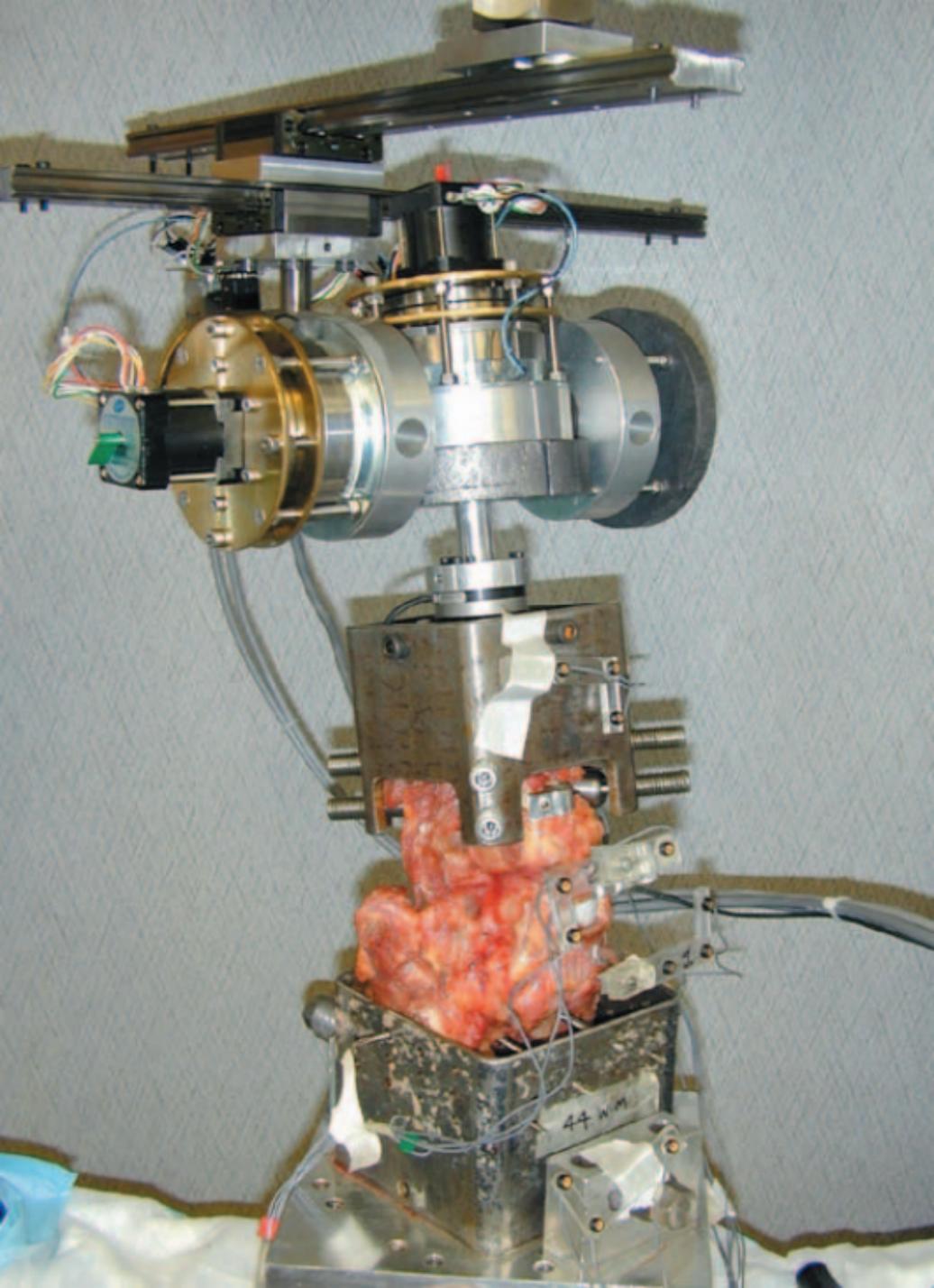
Figure 5: Operative level neutral zone (NZ) of anterior cervical reconstructions under axial rotation, flexion-extension, and lateral bending. Intact: intact C5-6 spinal segment; 3DF: 3-DF disc; Autograft: Autologous iliac bone graft; Auto+Plate: Anterior cervical plate fixation (Atlantis) with tricortical iliac bone graft. * -indicates a statistically significant difference from intact.
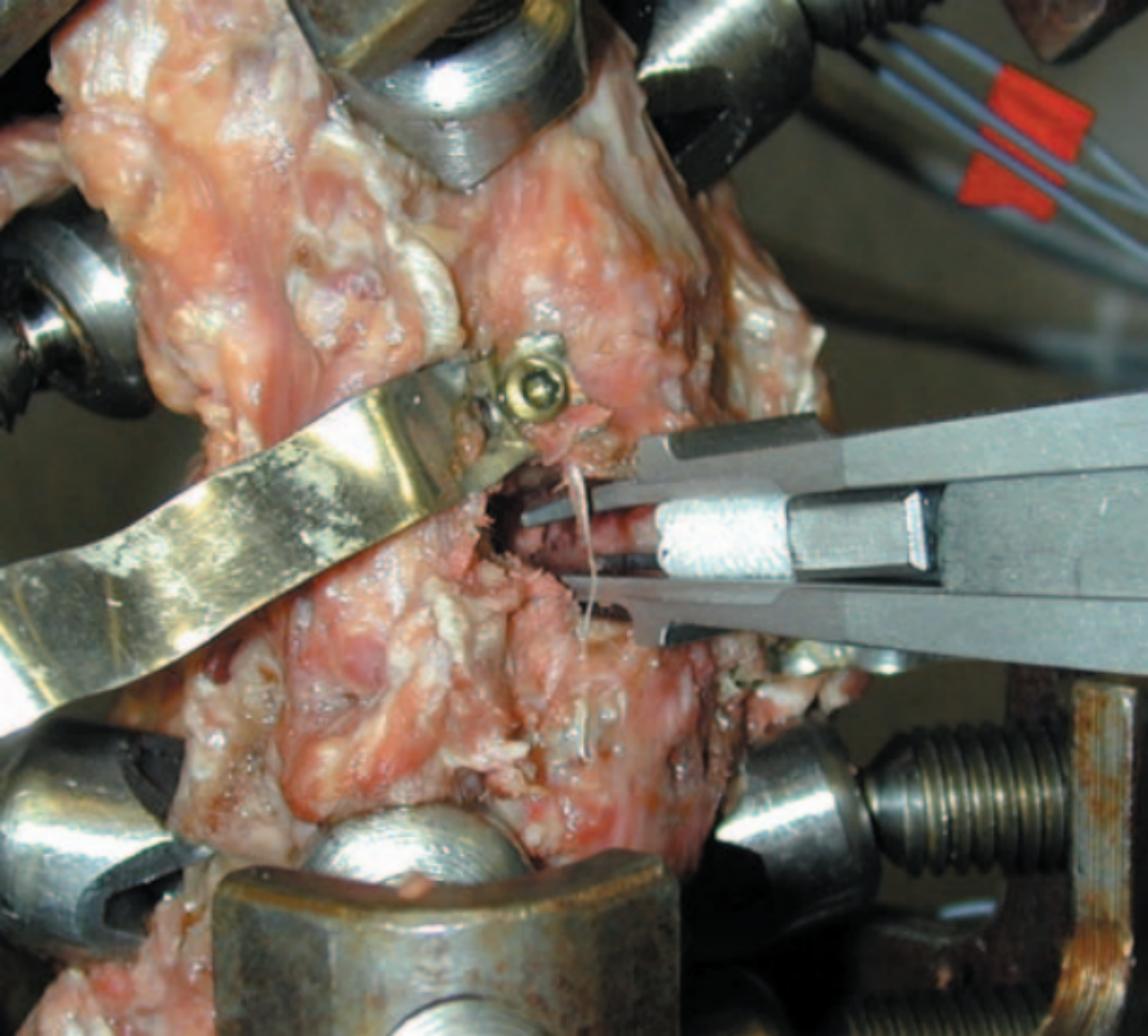
Figure 6: Upper adjacent level ROMs of anterior cervical reconstructions under axial rotation, flexion-extension, and lateral bending. Intact: intact C5-6 spinal segment; 3DF: 3-DF disc; Autograft: Autologous iliac bone graft; Auto+Plate: Anterior cervical pla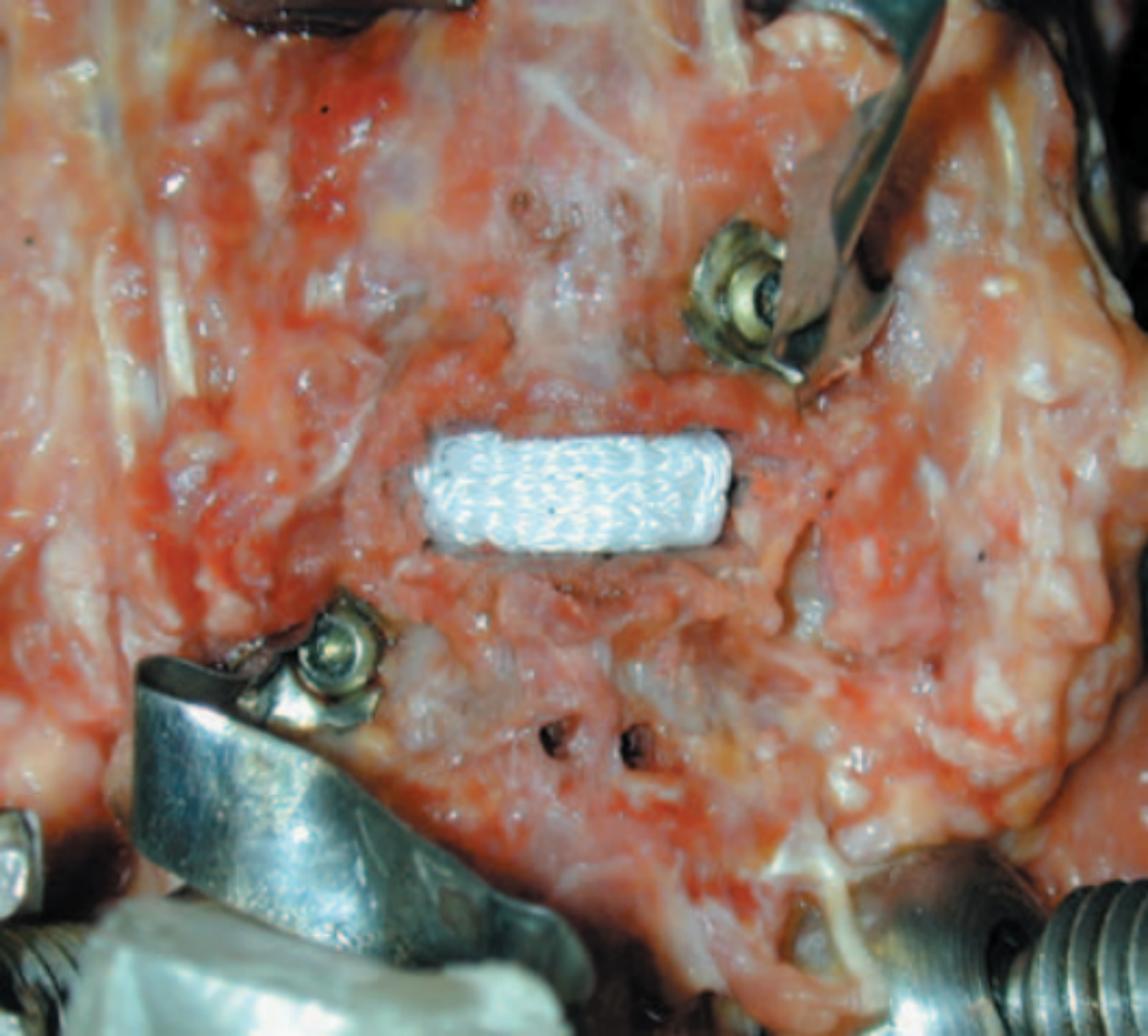te fixation (Atlantis) with tricortical iliac bone graft. * -indicates a statistically significant difference from intact.

Figure 7: Lower adjacent level ROMs of anterior cervical reconstructions under axial rotation, flexion-extension, and lateral bending. Intact: intact C5-6 spinal segment; 3DF: 3-DF disc; Autograft: Autologous iliac bone graft; Auto+Plate: Anterior cervical plate fixation (Atlantis) with tricortical iliac bone graft.
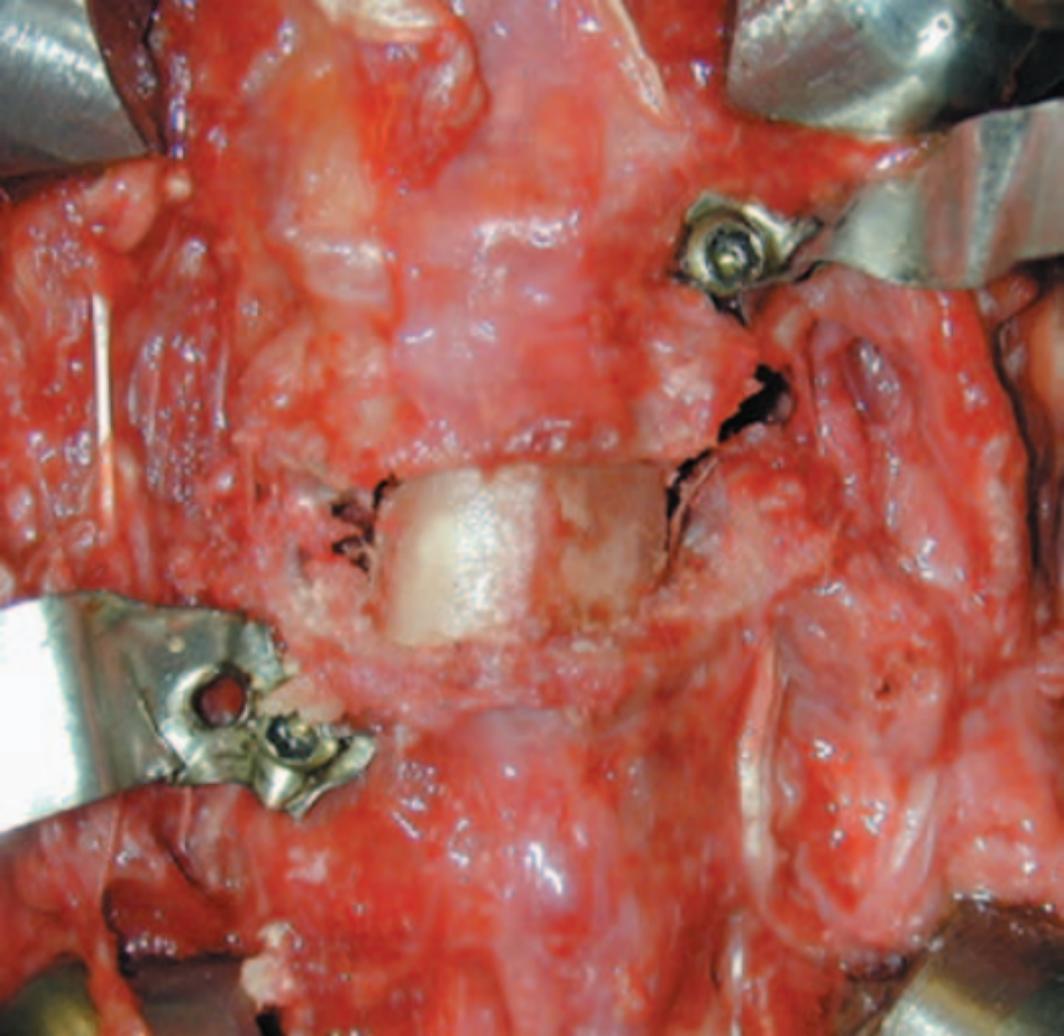
Figure showing Neutral Zone (% intact) versus Biomechanical Loading Mode for Intact, 3DF, Autograft, and Auto + Plate conditions across Axial Rotation, Flexion-Extension, and Lateral Bending.

**Biomechanical Loading Mode**

Legend: Intact, 3DF, Autograft, Auto + Plate

Y-axis: Range of Motion (% intact), 0 to 140
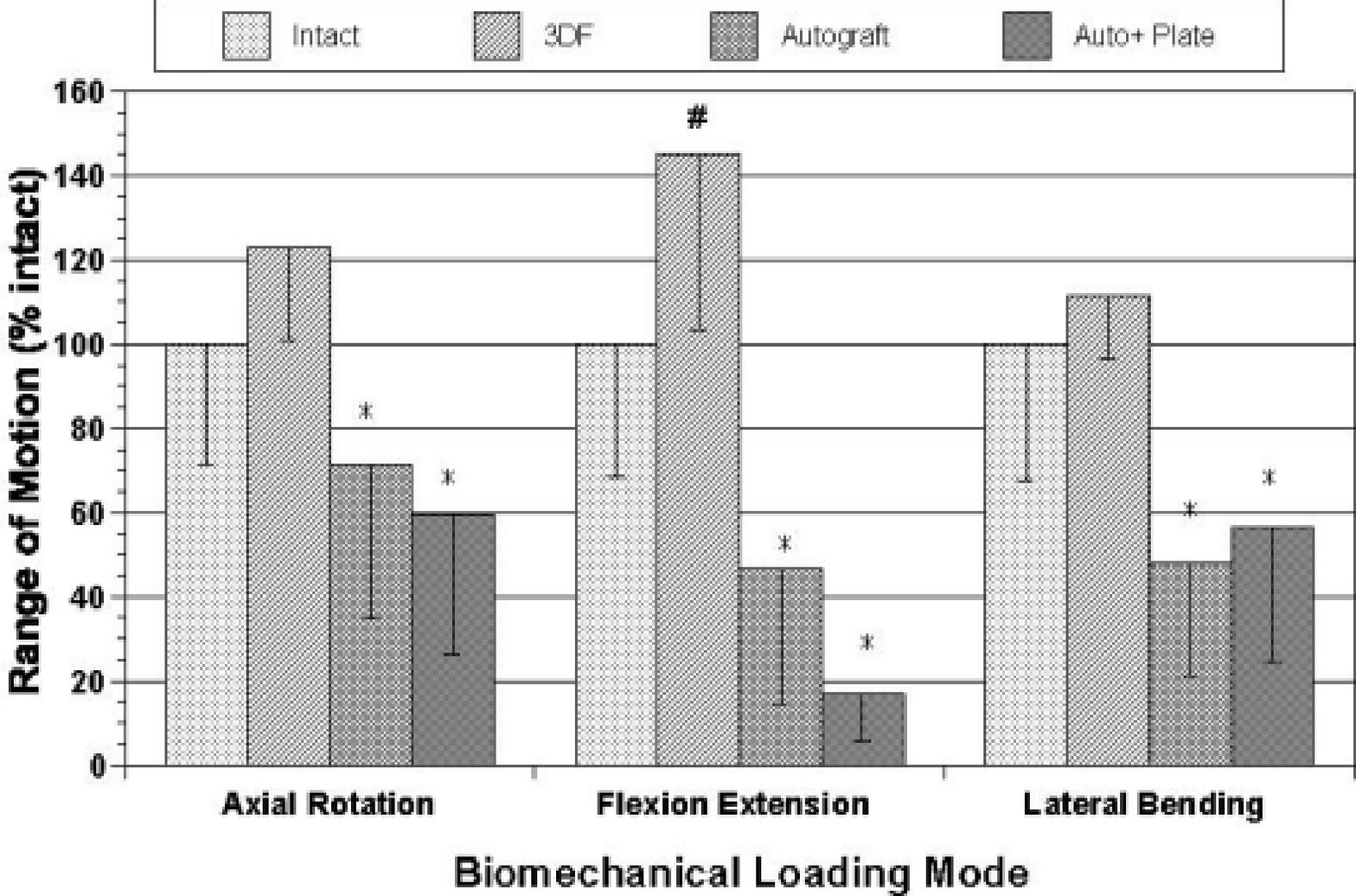
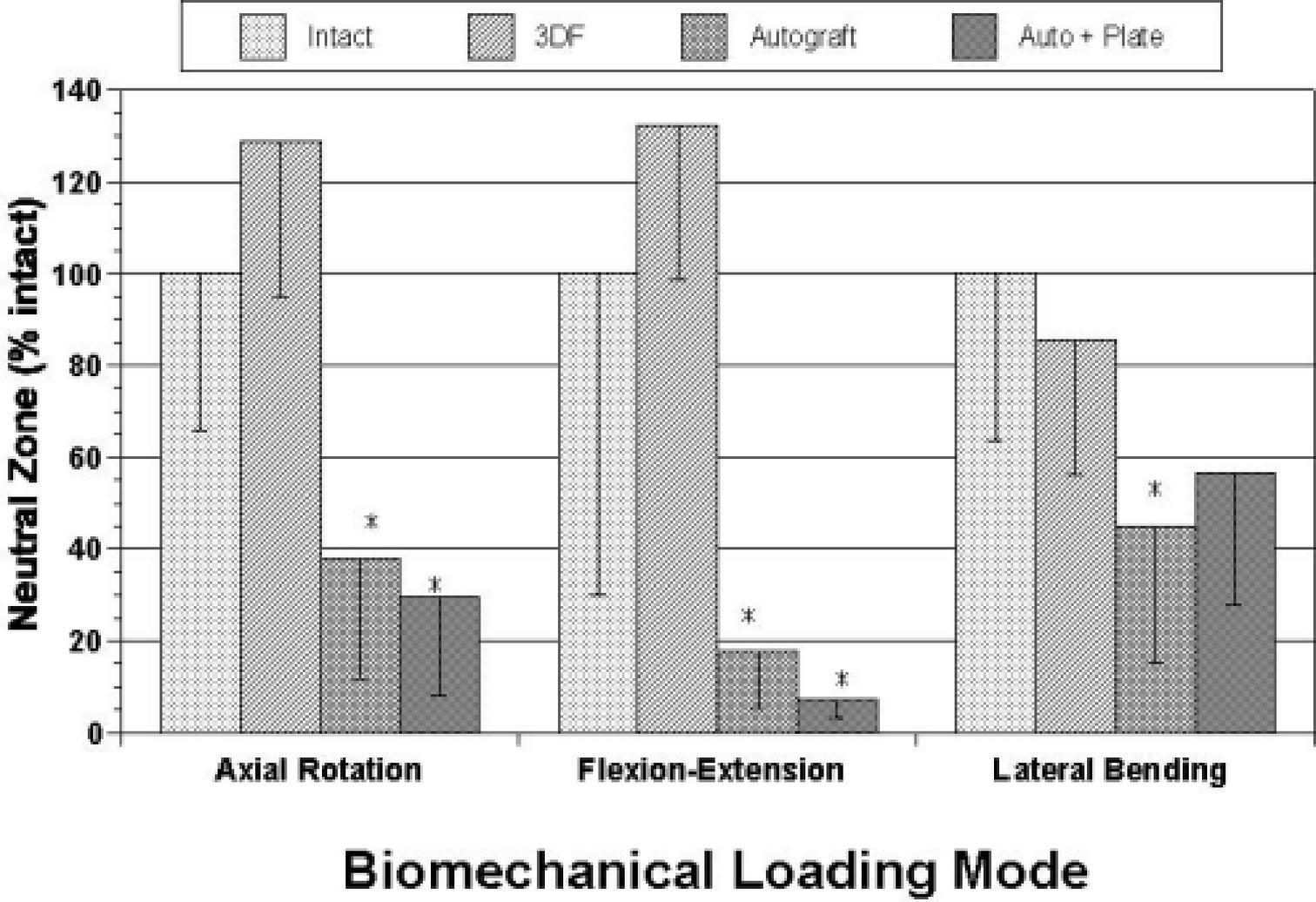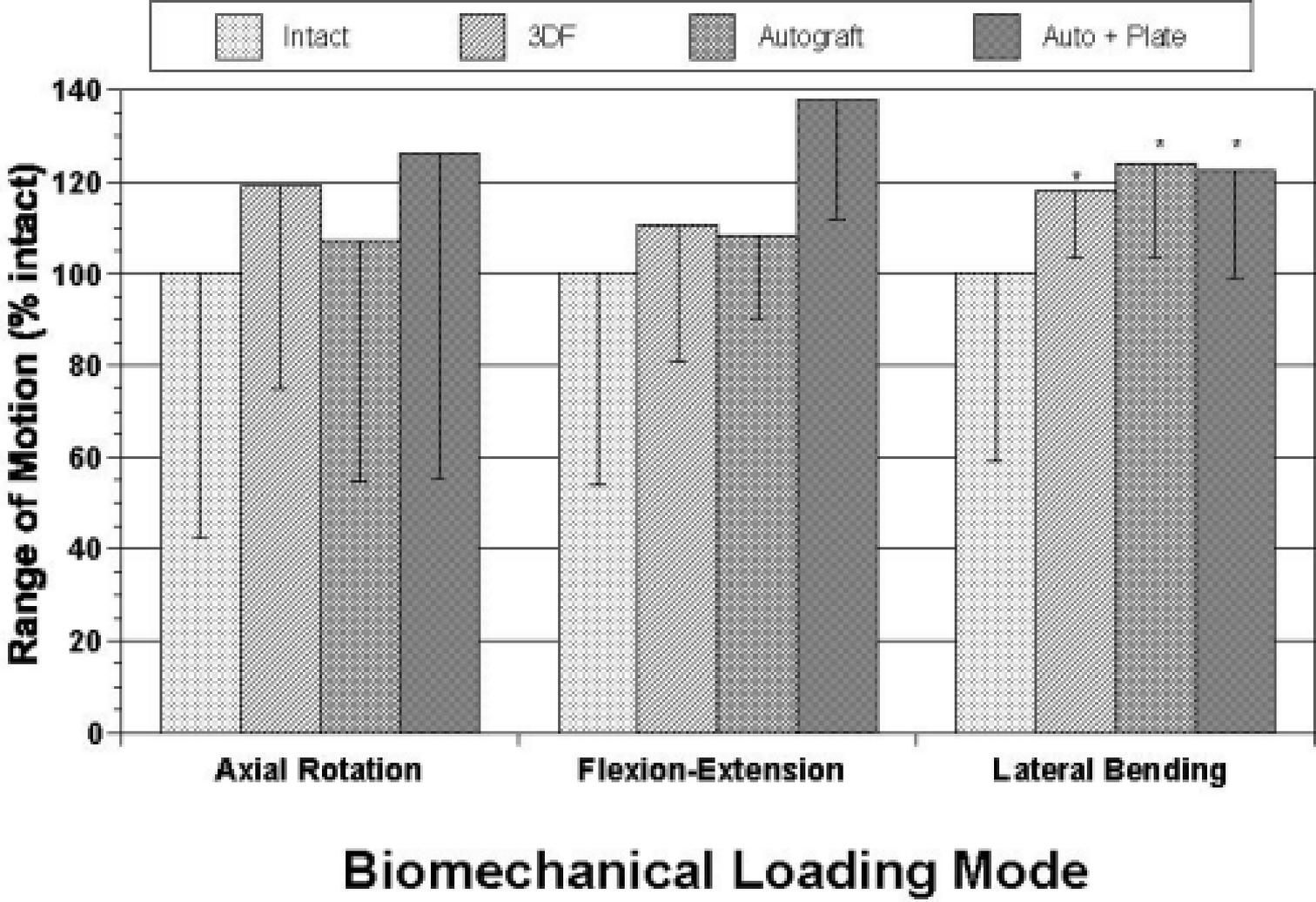X-axis categories: Axial Rotation, Flexion-Extension, Lateral Bending

**Lower Adjacent segment ROM: C6/7 level Cervical Disc Replacement**