Medical Devices: Evidence and Research

Dovepress
open access to scientific and medical research

Open Access Full Text Article

ORIGINAL RESEARCH

Biomechanical evaluation of DTRAX® posterior cervical cage stabilization with and without lateral mass fixation

This article was published in the following Dove Press journal:
Medical Devices: Evidence and Research
23 August 2016
Number of times this article has been viewed

Leonard I Voronov[1,2]
Krzysztof B Siemionow[3]
Robert M Havey[1,2]
Gerard Carandang[2]
Avinash G Patwardhan[1,2]

[1]Department of Orthopaedic Surgery and Rehabilitation, Loyola University Chicago, Maywood, [2]Musculoskeletal Biomechanics Laboratory, Edward Hines Jr. VA Hospital, Hines, [3]Department of Orthopaedics, University of Illinois College of Medicine at Chicago, Chicago, IL, USA

Introduction: Lateral mass screw (LMS) fixation with plates or rods is the current standard procedure for posterior cervical fusion. Recently, implants placed between the facet joints have become available as an alternative to LMS or transfacet screws for patients with cervical spondylotic radiculopathy. The purpose of this study was to evaluate the biomechanical stability of the DTRAX® cervical cage for single- and two-level fusion and compare this to the stability achieved with LMS fixation with rods in a two-level construct.

Methods: Six cadaveric cervical spine (C3–C7) specimens were tested in flexion–extension, lateral bending, and axial rotation to ±1.5 Nm moment without preload (0 N) in the following conditions: 1) intact (C3–C7), 2) LMS and rods at C4–C5 and C5–C6, 3) removal of all rods (LMS retained) and placement of bilateral posterior cages at C5–C6, 4) bilateral posterior cages at C4–C5 and C5–C6 (without LMS and rods), and 5) C4–C5 and C5–C6 bilateral posterior cages at C4–C5 and C5–C6 with rods reinserted.

Results: Bilateral posterior cervical cages significantly reduced range of motion in all tested directions in both single- and multilevel constructs ($P<0.05$). Similar stability was achieved with bilateral posterior cages and LMS in a two-level construct: 0.6°±0.3° vs 1.2°±0.4° in flexion–extension ($P=0.001$), (5.0°±2.6° vs 3.1°±1.3°) in lateral bending ($P=0.053$), (1.3°±1.0° vs 2.2°±0.9°) in axial rotation ($P=0.091$) for posterior cages and LMS, respectively. Posterior cages, when placed as an adjunct to LMS, further reduced range of motion in a multilevel construct ($P<0.05$).

Conclusion: Bilateral posterior cages provide similar cervical segmental stability compared with a LMS and rod construct and may be an alternative surgical option for select patients. Furthermore, supplementation of a lateral mass construct with posterior cages increases cervical spine stability in single- and multilevel conditions.

Keywords: cervical spine, posterior fusion, biomechanics, cervical facets, DTRAX cervical cage, lateral mass screw

Introduction

Posterior approaches to cervical spinal fusion significantly decrease the risk for dysphagia, but typically require nerve root manipulation and bone resection.[1] Lateral mass screw (LMS) fixation with plates or rods is the current standard procedure for posterior cervical fusion.[2] Recently, implants placed between the facet joints have become available as an alternative to LMS or transfacet screw for patients with cervical spondylotic radiculopathy. The procedure entails placement of a spacer or posterior cervical cage between the facet joints using a minimally disruptive posterior approach. Favorable results have been reported up to 2 years postoperatively with no significant change in cervical alignment.[3,4]

Correspondence: Leonard I Voronov
Musculoskeletal Biomechanics Laboratory, Edward Hines Jr. VA Hospital, 5000 South 5th Avenue, Hines, IL 60141, USA
Tel +1 708 202 5802
Fax +1 708 202 7938
Email Lvoronov@hotmail.com

submit your manuscript | www.dovepress.com
Dovepress
http://dx.doi.org/10.2147/MDER.S111031

Published biomechanical investigations have shown significant reductions in range of motion (ROM) and increased foraminal area using a variety of cervical implants placed between the facet joints.[5–9] However, no studies to date have compared the biomechanical effects of any of these implants to LMS constructs. The purpose of this study was to evaluate the biomechanical stability of one type of posterior cervical cage (DTRAX® Cervical Cage with Bone Screw, Providence Medical Technology, Walnut Creek, CA, USA) (Figure 1) in single- and two-level fusion and compare this to the stability achieved with LMS fixation with rods in a two-level construct.

Methods

Approval for this study was obtained from the Research and Development Committee of the Edward Hines Jr. VA Hospital for the use of human tissue. Six fresh-frozen human cadaveric cervical spine (C3–C7) specimens were obtained from a tissue bank accredited by the American Association of Tissue Banks (AATB). Radiographic screening was performed to exclude specimens with fractures, metastatic disease, osteoporosis, bridging osteophytes, or other conditions that could significantly affect spinal biomechanics. Specimen mean age (standard deviation) was 48.8 (6.6) years, four were male and two were female.

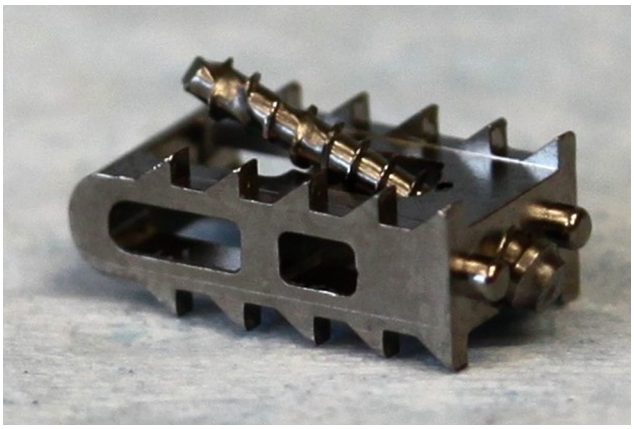

Figure 1 DTRAX® (Providence Medical Technology, Walnut Creek, CA, USA) cervical cage with bone screw.
Note: Cage dimensions are 10 mm × 5.5 mm × 2.5 mm. The bone screw extends 3.5 mm through the fenestration at the superior aspect of the cage.

All specimens were thawed and stripped of the paraspinal musculature while preserving the discs, facet joints, and osteoligamentous structures. The caudal vertebral body of each specimen was potted in an aluminum cup with polymethyl methacrylate bone cement. The cup was attached to a kinematic testing apparatus, while the cephalad end was not restrained. A moment was applied by controlling the flow of water into bags attached to loading arms fixed to the C3 vertebra. This apparatus allowed continuous cycling of the specimens between specified maximum moment endpoints in flexion–extension (FE), lateral bending (LB), and axial rotation (AR) (Figure 2). Load–displacement data were collected until two reproducible load–displacement loops were obtained. This generally required a maximum of three loading cycles.

The angular motion of the C3 to C6 vertebrae relative to C7 was measured using an optoelectronic motion measurement system (Model Certus, Optotrak©, Northern Digital, Waterloo, ON, Canada). In addition, biaxial angle sensors (Model 902-45, Applied Geomechanics, Santa Cruz, CA, USA) were mounted on each vertebra to allow for real-time feedback and to provide data redundancy in FE and LB. A six-component load cell (Model MC3A-6-1000, AMTI Inc., Newton, MA, USA) was placed under the specimen to measure the applied moments. Fluoroscopic imaging (OEC 9800 Plus, GE Healthcare, Salt Lake City, UT, USA) was used to document implant position.

Each specimen was tested in FE, LB, and AR to ±1.5 Nm moment without preload (0 N) in the following conditions: 1) intact (C3–C7), 2) LMS and rods at C4–C5 and C5–C6, 3) removal of all rods (LMS retained) and placement of bilateral posterior cages at C5–C6, 4) bilateral posterior cages at C4–C5 and C5–C6 (without LMS rods), 5) C4–C5

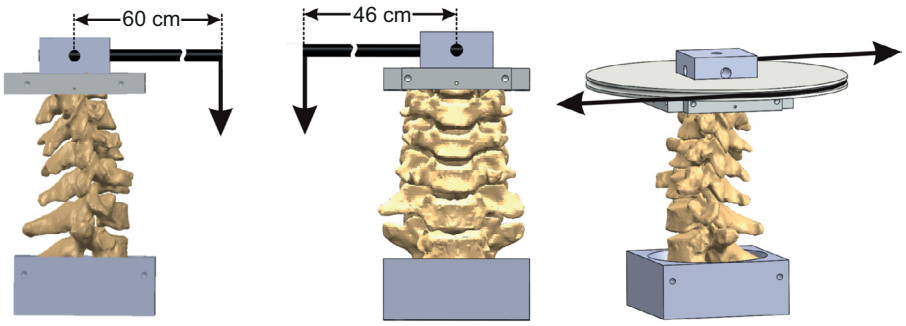

Figure 2 Experimental setup during flexion–extension testing.
Note: Angular motions of the C2–C7 vertebrae relative to T1 were measured using an optoelectronic motion measurement system.

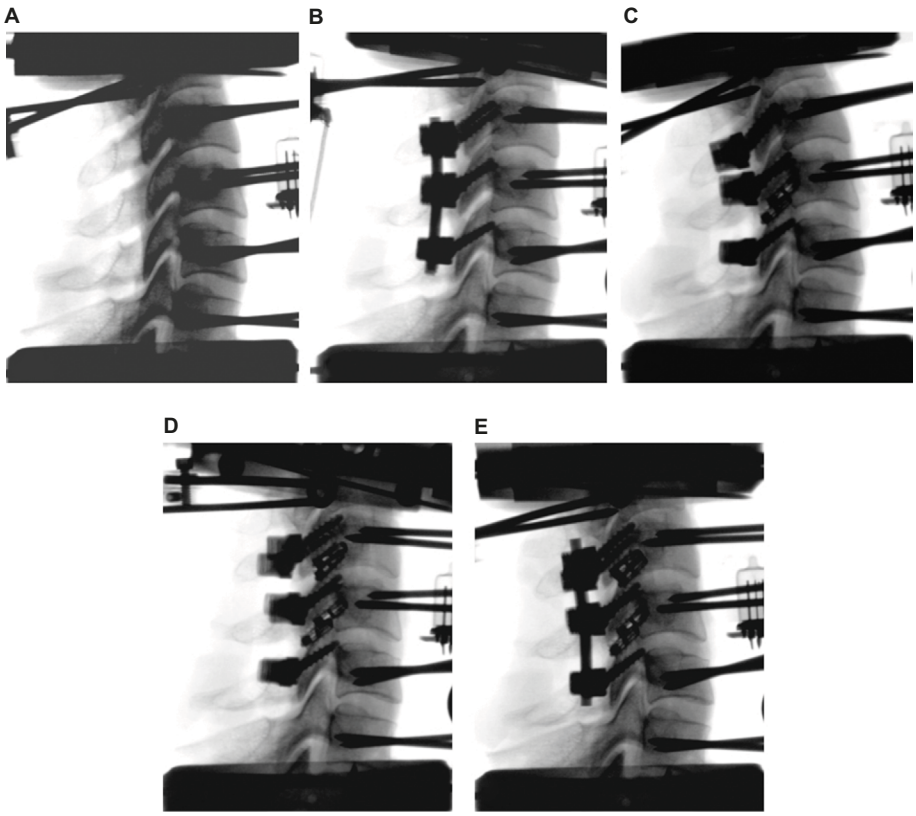

Figure 3 Testing protocol.
Notes: (A) Intact, **(B)** C4–C6 LMS construct, **(C)** C5–C6 bilateral posterior cages, **(D)** C4–C6 bilateral posterior cages, **(E)** C4–C6 LMS construct with supplemental bilateral posterior cages.
Abbreviation: LMS, lateral mass screw.

and C5–C6 bilateral posterior cages at C4–C5 and C5–C6 with rods reinserted (Figure 3).

Posterior cervical cages were placed bilaterally between the facet joints according to the manufacturer's surgical technique.[10] Briefly, the lateral mass adjacent to the posterior facet was decorticated with a trephine and distracted. The facet end plates were then decorticated with a rasp before deploying and anchoring the posterior cage into the facet. A bone screw was placed through the posterior cage with a caudal to cranial trajectory into the superior facet. This was repeated on the contralateral side.

LMS fixation was performed according to a standard surgical procedure (Solanas® Posterior Cervicothoracic Fixation System, Alphatec Spine, Carlsbad, CA, USA). After drilling a pilot hole, it was tapped and a load screw inserted. For fusion conditions, a custom rod was cut, contoured, placed, and secured using set screws. During posterior cage-only testing conditions, the load screws were retained and the rods were removed.

Statistical analysis

Segmental ROM was analyzed using paired *t*-tests. Significance level was set to alpha =0.05. The effect of bilateral posterior cages on segmental ROM was evaluated in a single- and two-level constructs as follows: C5–C6 intact vs bilateral posterior cages and C4–C6 intact vs bilateral posterior cages, respectively. The effect of bilateral posterior cages was compared to LMS fusion for a two-level condition at C4–C6. Finally the combination of the two constructs was tested by comparing posterior cages alone to posterior cages plus LMS at C4–C6.

Each comparison was analyzed separately for FE, LB, and AR, since no comparisons across load types were intended in the study design. The statistical data analyses were performed using Systat 10.2 software package (Systat Software, Richmond, CA, USA).

Results

Segmental ROM was significantly reduced in all tested directions for all evaluated constructs compared to intact motion. ROM decreased significantly after placement of bilateral posterior cages at a single level (C5–C6): 11.5°±3.5° to 3.4°±1.8° FE (P=0.001), 10.0°±2.1° to 0.7°±0.5° LB (P=0.000), and 8.5°±2.1° to 0.8°±0.5° AR (P=0.000) for intact and posterior cage conditions, respectively (Table 1). Similar results were observed for bilateral posterior cages at two levels. ROM

Table 1 Mean (SD) segmental ranges of motion (degree) for each condition under 0 N follower preload and 1.5 Nm load for each test condition

Motion segment/ testing mode	Intact	C4–C6 LMS fusion	C5–C6 posterior cages	C4–C6 posterior cages	C4–C6 posterior cages + LMS fusion
C3–C4					
Flexion–extension	9.0±2.5	10.1±2.5	10.1±2.6	10.2±2.5	10.1±2.5
Lateral bending	11.2±3.0	10.6±2.2	11.1±2.5	10.4±2.5	10.5±2.3
Axial rotation	6.9±2.4	8.0±2.5	8.1±2.7	8.9±2.7	8.8±2.6
C4–C5					
Flexion–extension	8.6±2.0	1.4±0.7	9.8±1.8	2.0±1.1	1.2±0.7
Lateral bending	9.8±1.2	0.5±0.2	9.3±1.5	0.1±0.3	0.3±0.2
Axial rotation	9.3±3.2	1.0±0.6	10.0±3.3	0.5±0.3	0.5±3.3
C5–C6					
Flexion-extension	11.5±3.5	1.6±0.7	3.4±1.8*	3.1±1.7	1.1±0.6
Lateral bending	10.0±2.1	0.7±0.3	0.7±0.5*	0.5±0.5	0.4±0.3
Axial rotation	8.5±2.1	1.2±0.4	0.8±0.5*	0.8±0.6	0.5±0.2
C6–C7					
Flexion–extension	9.3±1.6	8.7±2.9	8.5±3.2	8.8±2.9	8.8±3.2
Lateral bending	6.7±2.1	6.1±3.2	6.1±3.3	6.4±3.3	6.4±3.3
Axial rotation	4.7±1.8	4.2±2.4	4.5±2.3	4.7±2.3	4.6±2.6
C4–C6					
Flexion–extension	20.2±5.2	3.1±1.3*	12.5±3.5	5.0±2.6*	2.2±1.2*
Lateral bending	10.8±2.6	1.2±0.4*	10.0±1.6	0.6±0.3*	0.7±0.3*
Axial rotation	17.8±5.1	2.2±0.9*	10.8±3.6	1.3±1.0*	1.0±0.5*

Note: *Significance from intact at $P<0.05$.
Abbreviations: LMS, lateral mass screw; SD, standard deviation.

at C4–C6 decreased from the intact condition as follows: 20.2°±5.2° to 5.0°±2.6° in FE ($P=0.000$), 10.8°±2.6° to 0.6°±0.3° in LB ($P=0.000$), and 17.8°±5.1° to 1.3°±1.0° in AR ($P=0.001$) (Table 1).

Two-level fusion at C4–C6 with bilateral posterior cages showed a significant reduction in motion compared to fusion with LMS in LB: 0.6°±0.3° vs 1.2°±0.4°, posterior cages and LMS, respectively ($P=0.001$). While significance in FE was not reached, there was a strong trend for reduced motion with LMS (5.0°±2.6° vs 3.1°±1.3°) ($P=0.053$). In AR, there was no difference between the implants (1.3°±1.0° vs 2.2°±0.9°) ($P=0.091$).

Supplementing LMS fusion with bilateral posterior cages in a two-level construct significantly reduced motion compared to LMS alone (Table 2). Mean ROM value decreased from 3.1°±1.3° to 2.2°±1.2° (posterior cages, LMS, respectively) in FE ($P=0.030$) and from 2.2°±0.9° to 1.0°±0.5° in AR ($P=0.016$). There was no statistical significance between groups in LB (1.2°±0.4° vs 0.7°±0.3°) ($P=0.076$).

Discussion

Several surgical treatment options are available for patients suffering from cervical radiculopathy. Previous studies report favorable clinical and radiographic outcomes in patients with single-level cervical radiculopathy secondary to spondylosis treated with posterior cervical spacers or cages placed between the facet joints.[5,11] The current study demonstrated that both lateral mass constructs and bilateral posterior cervical cages offer comparable postoperative segmental stability; both techniques significantly decreased cervical ROM in FE, LB, and AR. Failure to provide adequate stabilization may lead to deformity or other types of instability that may contribute to neurological deterioration.[12] In this study, supplementation of lateral mass constructs with bilateral posterior cervical cages further significantly decreased cervical ROM in FE and AR. Potential clinical implications include enhancing the stability of LMS to promote fusion in cases of compromised bone quality where LMS purchase may be in question, or as a supplementary minimally invasive technique to improve stabilization in a case of LMS instrumentation failure or inadequacy.

There were some differences in the degree of stability conferred by each construct; LMS provided greater stability in FE and posterior cervical cages were more stable in LB. Implant choice should be based on clinical and anatomical considerations. Certain clinical scenarios, such as cervical fracture dislocations, may require preferential stability in one plane of movement. Scenarios in which FE stability are of greater importance may be managed with LMS constructs, while the most unstable situations would benefit from LMS augmented with bilateral posterior cages. The degree of

Table 2 Differences across conditions at C4–C6 using one-way ANOVA with Bonferroni correction

C4–C6 ROM – Paired *t*-test statistics: *P*-values (three comparisons)	Intact vs posterior cages	Posterior cages vs LMS	LMS vs LMS with posterior cages
Flexion–extension	0.000	0.014	0.030
Lateral bending	0.000	0.867	0.076
Axial rotation	0.001	0.784	0.016

Abbreviations: ANOVA, analysis of variance; LMS, lateral mass screw; ROM, range of motion.

stabilization required to promote successful arthrodesis while minimizing morbidity and implant failure has yet to be adequately quantified. For the majority of one- and two-level fusions, both constructs provide sufficient stability. Bilateral posterior cage construct has the advantage of providing indirect foraminal decompression and can be placed in a minimally disruptive fashion.[9,10] Further, this method may reduce perioperative morbidity associated with LMS by decreasing operative time, blood loss, and muscle disruption. This approach avoids potential screw-related complications such as injury to the sensitive anatomical structures of the cervical spine such as nerve root, spinal cord, and vertebral artery injuries.[13] Furthermore, the present analysis provides evidence to support the use of bilateral posterior cervical cages in settings where LMS is contraindicated, including lateral mass hypoplasia, congenital malformations, and prior LMS failure necessitating posterior revision instrumentation and fusion.

Maulucci et al investigated the effect of a 2 mm cortical facet spacer on foraminal area and segmental stability in conjunction with LMS and bilateral rods.[7] Bilateral spacers in both single- and three-level constructs increased foraminal height and provided increased segmental stability, although the kinematic results were not statistically significant. The data reported by the authors showed decreased segmental motion with larger spacers. The results reported by Maulucci et al are not concordant with the results obtained with the posterior cervical cage reported in our biomechanical study. This may be due to the shape and material of the implant, as well as the placement technique. Furthermore, Maulucci et al tested the facet spacer in a three-level construct, while we limited testing to single- and two-level constructs.

As with all studies, this investigation has limitations. While cadaveric specimens were not modified to simulate pathologic conditions, age-appropriate specimens were used in this study. The kinematic evaluation performed herein is reflective of the immediate postoperative condition. Muscles act to stabilize the spine by exerting a compressive preload across spinal segments. This study was intended to assess the implants under a worst-case scenario.[14] Therefore, our cadaveric model did not include compressive loading. Cyclical loading conditions were not evaluated; thus, the long-term in vivo effects of each testing condition are unknown. Further limitations include a sequential testing mode. While it is not suspected to affect ROM, the two-level posterior cage testing was performed with LMS (without rods) in place. This testing sequence was chosen to fully utilize each specimen. Kinematics vary by spinal level; comparisons are best made before and after surgeries at the same level. Finally, the change in cervical lordosis was not assessed in this study. This characteristic may be of importance in preserving cervical balance and muscular alignment.[15–18]

Conclusion

In conclusion, bilateral posterior cages provide similar cervical segmental stability compared to an LMS and rod construct and may be an alternative to LMS for select patients, particularly in conditions where a lateral mass approach is contraindicated. Furthermore, supplementation of a lateral mass construct with posterior cages increases cervical spine stability in single- and multilevel conditions.

Acknowledgments

Funding for this study was provided by the Rehabilitation Research and Development Service, Department of Veterans Affairs (Grant 1-I01-RX-001269-01-A2), Washington DC, and Providence Medical Technology, Walnut Creek, CA, USA. The authors wish to thank Robyn Capobianco for manuscript assistance.

Disclosure

KB Siemionow is a consultant for Providence Medical Technology. LI Voronov, RM Havey, G Carandang, and AG Patwardhan have no conflicts of interest in this work and have full control of all data.

References

1. Radcliff KE, Koyonos L, Clyde C, et al. What is the incidence of dysphagia after posterior cervical surgery? *Spine (Phila Pa 1976)*. 2013;38(13):1082–1088.
2. Coe JD, Vaccaro AR, Dailey AT, et al. Lateral mass screw fixation in the cervical spine: a systematic literature review. *J Bone Jt Surg Am*. 2013;95(23):2136–2143.
3. Tan LA, Straus DC, Traynelis VC. Cervical interfacet spacers and maintenance of cervical lordosis. *J Neurosurg Spine*. 2015;22(5):466–469.
4. McCormack BM, Bundoc RC, Ver MR, Ignacio JMF, Berven SH, Eyster EF. Percutaneous posterior cervical fusion with the DTRAX facet system for single-level radiculopathy: results in 60 patients. *J Neurosurg Spine*. 2013;18(3):245–254.

5. Goel A, Shah A. Facetal distraction as treatment for single- and multi-level cervical spondylotic radiculopathy and myelopathy: a preliminary report. *J Neurosurg Spine*. 2011;14(6):689–696.
6. Tan LA, Gerard CS, Anderson PA, Traynelis VC. Effect of machined interfacet allograft spacers on cervical foraminal height and area. *J Neurosurg Spine*. 2014;20(2):178–182.
7. Maulucci CM, Sansur CA, Singh V, et al. Cortical bone facet spacers for cervical spine decompression: effects on intervertebral kinetics and foraminal area. *J Neurosurg Spine*. 2016;24(1):69–76.
8. Leasure JM, Buckley J. Biomechanical evaluation of an interfacet joint decompression and stabilization system. *J Biomech Eng*. 2014;136(7):071010.
9. Siemionow K, Janusz P, Glowka P. Cervical cages placed bilaterally in the facet joints from a posterior approach significantly increase foraminal area. *Eur Spine J*. 2016;25(7):2279–2285.
10. Siemionow K, McCormack BM, Menchetti PPM. Tissue sparing posterior cervical indirect decompression and fusion in foraminal stenosis. In: Menchetti PP, editor. *Cervical Spine: Minimally Invasive and Open Surgery*. New York, NY: Springer; 2015:135–148.
11. Traynelis VC, Sherman J, Nottmeier E, et al. Kinetic analysis of anterior cervical discectomy and fusion supplemented with transarticular facet screws. *J Neurosurg Spine*. 2014;20(5):485–491.
12. McAllister BD, Rebholz BJ, Wang JC. Is posterior fusion necessary with laminectomy in the cervical spine? *Surg Neurol Int*. 2012;3(Suppl 3):S225–S231.
13. Heller JG, Silcox DH, Sutterlin CE. Complications of posterior cervical plating. *Spine*. 1995;20(22):2442–2448.
14. de Koning CH, Heuvel S, Staal JB, Smits-Engelsman BC, Hendriks EJ. Clinimetric evaluation of methods to measure muscle functioning in patients with non-specific neck pain: a systematic review. *BMC Musculoskelet Disord*. 2008;9(1):142.
15. Panjabi MM, Cholewicki J, Nibu K, Grauer J, Babat LB, Dvorak J. Critical load of the human cervical spine: an in vitro experimental study. *Clin Biomech Bristol Avon*. 1998;13(1):11–17.
16. Beinert K, Keller M, Taube W. Neck muscle vibration can improve sensorimotor function in patients with neck pain. *Spine J Off J North Am Spine Soc*. 2015;15(3):514–521.
17. Cheng CH, Cheng HYK, Chen CPC, et al. Altered co-contraction of cervical muscles in young adults with chronic neck pain during voluntary neck motions. *J Phys Ther Sci*. 2014;26(4):587–590.
18. Cheng CH, Lin KH, Wang JL. Co-contraction of cervical muscles during sagittal and coronal neck motions at different movement speeds. *Eur J Appl Physiol*. 2008;103(6):647–654.