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April 8, 2019

Jeffrey C. Wang, MD, President
North American Spine Society
7075 Veterans Blvd.
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SUBJECT: NASS Draft Model Coverage Policy on Interspinous Fixation with Fusion

Dear Dr. Wang:

On behalf of the American Association of Neurological Surgeons (AANS), the Congress of Neurological Surgeons (CNS) and the AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves (DSPN), we appreciate the opportunity to comment on the North American Spine Society's (NASS') draft model coverage policy recommendation for Interspinous Fixation with Fusion.

We agree that interspinous process fixation to achieve an arthrodesis is a relatively new way to supplement a lumbar fusion construct, and has not been widely adopted by neurosurgeons at this time. While we concur with the statement in the NASS draft that, "There is still limited evidence published about outcomes of such devices," we would offer the following comments on the draft policy:

- **Indications for Use.** At the end of page 3, there is a statement that is confusing and seemingly contradictory. First, it stated that "The literature supports the use … with any of the following … 3. Interbody fusion of the same motion segment." Then the next paragraph stated "No literature supports the use … without performing an open decortication and fusion of the posterior bony elements." These two sentences are confusing as written. We recommend that the NASS authors consider changing the second sentence to read "No literature supports the use … without performing an open decortication and fusion of the posterior bony elements or interbody fusion."

- **Huang et al. Study**. On page 4, the sentence "Huang et al published a prospective randomized study comparing posterior lumbar interbody fusion comparing interspinous fixation with pedicle screws" is confusing. Based on the referenced article, did the NASS authors intend the sentence to read "Huang et al. published a prospective randomized study comparing supplementing posterior lumbar interbody fusion using either interspinous fixation or pedicle screws?"

- **Literature Review**. Generally, all the referenced articles are limited in value because of a small study population. More importantly, the direct comparison of the functional outcome using interspinous fixation to the currently most accepted treatment option with pedicle screws for either open fusion or interbody fusions is very limited. In addition, the articles that are published seem to show some concerns. For example, Lee's paper showed increased spondylolisthesis in the interspinous fixation group, and Chen's paper showed five interbody implant retropulsions out of 39 patients in a similar group. That number of retropulsions is concerning when a comparison to Fessler's study on 513 patients who underwent minimally invasive spinal transforaminal lumbar interbody fusion (MIS-TLIF) demonstrated only five retropulsions.[1] We believe that Fessler's study is a relevant study to include.

Conclusion

Overall, we agree that the evidence for supporting the usage of the interspinous fixation device to supplement lumbar fusion remains limited at this time. A multi-center, large prospective, randomized trial would be needed to compare the interspinous fixation device with pedicle screw fixation in open or interbody lumbar fusion to demonstrate the non-inferiority or advantage but is unlikely to happen. The accumulation of registry data will be the most plausible means to collect data.

There is currently available ample evidence and literature to support the use of interspinous fixation device for augmenting an interbody and/or a posterior fusion. We agree that this technology should remain an option for surgeons to achieve the arthrodesis of a lumbar segment.

Thank you for the opportunity to express our views.

Sincerely,

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Reference:

1. Bakhsheshian J, Khanna R, Choy W, Lawton CD, Nixon AT, Wong AP, Koski TR, Liu JC, Song JK, Dahdaleh NS, Smith ZA, Fessler RG. Incidence of graft extrusion following minimally invasive transforaminal lumbar interbody fusion. *J Clin Neurosci.* 2016;24:88-93.