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Radiographic Evaluation of a Novel Interspinous/Interlaminar Fusion Implant (Coflex-F™) System to Augment Lumbar Interbody Fusion*H. Afshar¹, M. Eif², H. Schenke², J.D. Auerbach³*¹Klinikum Leer, Leer, Germany, ²Klinikum Goerlitz, Gorlitz, Germany, ³Bronx-Lebanon Hospital Center, New York, NY, United States

Intro: Lumbar interbody fusion, either via a transforaminal, lateral, or anterior lumbar approach, remains the treatment of choice for many degenerative conditions of the lumbar spine. While certain interbody grafts are designed as a stand-alone construct, the majority of interbody fusions are augmented with posterior stabilization. Most commonly, lumbar pedicle screw instrumentation is used, but this technique is associated with a potentially morbid posterior lumbar spine approach, pedicle screw instrumentation which has the potential for neurovascular injury, and higher implant costs. The optimal posterior stabilization device following lumbar interbody fusion would be inserted in a minimally-invasive fashion, avoid excessive radiation, produce minimal soft-tissue damage, and avoid proximity to the neural structures. In contrast to other interspinous fusion plates, the Coflex-F™ (Paradim Spine) interspinous/interlaminar fusion device is a novel, minimally-invasive fusion implant that is placed in between adjacent spinous processes following lumbar interbody fusion, with the stabilizing U-portion of the device providing significant stability to the construct by fixating onto the strong lamina bone, not the more cancellous spinous processes. The purpose of the current study is to report the radiographic data from a multicenter European trial in which the Coflex-F™ device was used to stabilize a lumbar interbody fusion.

Methods: A multicenter European clinical trial was performed to treat patients with degenerative disc disease with lumbar interbody fusion supplemented by Coflex-F™ interspinous fusion implant. A total of 6 surgeons participated in the trial. The diagnoses included degenerative disc disease, up to Grade 1 degenerative spondylolisthesis, disc herniation, and recurrent disc herniation. A total of 90 subjects were enrolled and have been followed up radiographically ranging from 6-24 months post-operatively. Radiographic assessments included

- 1) evidence of bridging bone,
- 2) < 3mm translational motion
- 3) < 5 degrees of angular motion, and
- 4) fusion success.

A board-certified, independent radiologist performed radiographic assessments.

Results: Of the 90 patients enrolled in the study, 81 patients (90%) had complete radiographic data that permitted assessment of fusion status. Sixty-five patients had flexion-extension films, and 62 patients had all radiographic measures available for review. The fusion rate, using established radiographic criteria,

was 95.2% (59/62). Specifically, bridging bone was present in 96.3% (78/81), 100% of patients (65/65) had < 3mm translational motion, and 100% (65/65) had < 5 degree of angular motion. Of note, however, 2 of the 3 patients that did not exhibit bridging bone were only 6 weeks post-operatively, and would not be expected to show bridging bone at this early timepoint. Excluding these 3 patients, the fusion rate is 100%.

Discussion: Posterior stabilization to augment lumbar interbody fusion was successfully achieved using the Coflex-F™ device, a minimally-invasive interspinous/interlaminar fusion implant system, which produced a fusion rate of 100% for patients who had at least 3 months follow-up. This posterior stabilization device allows for soft-tissue sparing, reduced blood loss, reduced surgical time, an improved safety profile by avoiding pedicle screw placement and possibly proximity to neural structures, and reduced implant costs. The Coflex-F™ device is an attractive alternative to pedicle screw-based systems to augment lumbar interbody fusion device stabilization.