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A Comparison of Short Form-12 Health-Related Quality of Life Improvements following coflex® Interlaminar Stabilization, Lumbar Spinal Fusion with and without Cages, and Total Joint Arthroplasty

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Summary
The coflex® interlaminar device facilitates superior SF-12 PCS and equivalent SF-12 MCS Health-Related Quality of Life (HRQoL) outcomes compared with posterolateral fusion in the treatment of spinal stenosis with degenerative spondylolisthesis. Further, the results with coflex® were comparable to reported outcomes following total joint replacement, and posterior lumbar interbody fusion. Coflex® interlaminar stabilization is a less-invasive, motion-preserving alternative to fusion that yields equivalent or superior HRQoL outcomes to the gold standard spinal fusion, and to total joint replacement.

Background
Health-related Quality of Life Outcome (HRQoL) measures in spinal surgery have become increasingly important to characterize and quantify improvements in life quality and to justify continued utilization. The purpose of the current study is to report the 2-year Short Form 12 (SF-12) results from a randomized, multicenter, prospective, FDA IDE trial comparing coflex® interlaminar stabilization with laminectomy and posterolateral spinal fusion without cages (PLF), and to compare these results with previously reported (by senior author W.R.S.) SF-12 outcomes following total knee arthroplasty (TKA), total hip arthroplasty (THA), and posterior lumbar interbody fusion (PLIF) to treat degenerative spondylolisthesis.

Methods
219 subjects with spinal stenosis and up to Grade 1 spondylolisthesis received coflex® interlaminar device (n=146) or PLF (n=73). SF-12 Physical Component Score (PCS) and Mental Component Score (MCS) were collected at baseline and 24 months. These subjects were compared with data from historical controls.

Results
At 2 years, mean improvements experienced by the coflex® group (15.8; 95% CI: 13.2-18.3, $p<0.0001$) and the PLF group (12.6; 95% CI: 8.7-16.4, $p<0.0001$) were comparable or favorable to TKA (8; 95% CI: 7-9), THA (11; 95% CI: 9-13), and PLIF (11; 95% CI: 9-14). Coflex® patients had significantly higher SF-12 PCS means at 2 years (44.8; 95% CI: 42.6-47.0) compared with PLF (40.3; 95%CI:37.0-43.6, $p=0.027$), and had comparable outcomes to normal, unaffected controls (44; 95% CI: 43-46), TKA (37; 95% CI:34-43), THA (43; 95% CI: 41-44), and PLIF (39; 95% CI: 37-42). Mean improvement in SF-12 MCS was similar in coflex® (5.9; 95% CI:3.5-8.3) and PLF (5.6; 95% CI: 1.9-9.2), and both groups achieved levels similar to unaffected controls.

Conclusion
The coflex® interlaminar is superior to PLF in SF-12 PCS at 2years, comparable to reported outcomes following PLIF, and comparable to reported TJA outcomes, the current benchmark for HRQoL success. Coflex® interlaminar stabilization is a less-invasive, motion-preserving alternative to fusion that yields equivalent or superior HRQoL outcomes compared to the gold standard spinal fusion, and to TJA.