Early 3-Month Cervical Outcomes of the Fortilink®-C Interbody Fusion System with TETRAfuse® 3D Technology In Subjects With Degenerative Disc Disease Study – The FORTE Study

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Disclosures

Consulting and Product Development
- CoreLink
- Stryker
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Introduction

The novel 3D printed porous and radiolucent PEKK (PolyEtherKetoneKetone) or Fortilink® Interbody Fusion (IBF) Systems has osteointegrative characteristics providing a favorable fusion platform with bone-like mechanical properties.

The FORTE study is a multi-center prospective, post-market study being conducted to assess the real-world clinical use of the 3D printed PEKK IBFs enrolling a total of 150 patients with 50 patients in each cervical, lateral lumbar and transforaminal lumbar cohorts.
Methods

This interim 3-month analysis assessed subjects that underwent a cervical procedure implanted with the PEKK cervical IBF and have completed 3 months of post-op follow-up.
Results

The analysis includes fourteen (14) subjects. The average procedure duration was 98.8 minutes with an average estimated blood loss of 40 ccs, and an average length of hospital stay to discharge of 0.5 days post-op. The ViBone® Viable Bone Matrix (VBM) cellular allograft was used as the bone void filler for all subjects. The average change in NDI from baseline was statistically significant with a change from 48.4 to 32.9, indicating an improvement from severe disability to moderate disability.
The average change in VAS Neck Pain score from baseline was statistically significant with a change from 69.7 to 44.8. The average change from baseline for VAS Left Arm and VAS Right Arm pain scores were not statistically significant but both pain scores decreased respectively by -28.4 and -9.7.
Results (cont)

Thirteen of the fourteen subjects (92.9%) are satisfied with the PEKK cervical IBF and would recommend the procedure.

There are no reports of device and instrument related adverse events.
71-year-old female with neck pain and bilateral shoulder and arm radiculopathy, left much worse than right
Conclusion

The early results from the cervical cohort of the FORTE study show that the novel 3D printed porous PEKK IBF is safe and demonstrated statistically significant improvement in pain. As the FORTE study progresses, long-term follow-up data will evaluate the prolonged safety and performance of the novel PEKK IBF devices.