Carbon Fiber Pedicle Screws: Evolution of Spinal Fusion Hardware for improved patients follow-up

Prof. R. Gepstein¹, Dr. I. Engel¹, Dr. E. Barbalak², Prof. Y. Folman²

**Background:** Spinal fusion using pedicle screws made out of stainless steel or titanium is a common practice in the past few decades. However, metal hardware interfere with current imaging modalities like CT & MRI, creating artifacts. This prohibits visualization of nerve & soft tissue structures surrounding the pedicle screws. Clear visualization is especially important in spine tumors. These patients are treated with adjunctive radiation therapy. In case of metal hardware, radiation distribution is effected due to backscatters.

Recently, a pedicle screw system made out of CFR-PEEK has been introduced (CarboFix Orthopedics Ltd.). The system includes poly-axial carbon fiber pedicle screws, in which the screw threads are coated with an ultrathin titanium shell, to enable X-ray visualization and to improve bone integration. The screw tulip, locking element and rods are made out of carbon fibers as well, and marked with a minute tantalum radiopaque thread. Surgical technique is similar to that of other metal systems.

In our study, performed at the Herzeliya MC & Hillel-Yaffee MC, we have evaluated the safety and efficacy of the system (CarboClear Pedicle Screw System) for thoracolumbar and sacral spine fusion.

**Methods:** 30 patients (15 F & 15 M) suffering from one or more of the following: Spondylolisthesis, Spinal Stenosis and Disc Herniation were enrolled. Fusion was evaluated by standard radiograms with or without MRI/CT scans. Quality of life assessed by dedicated questionnaires. These were performed at 1, 3, 6 and 12 months post-op.

**Results:** First cases were performed back in 2013. All operations were completed successfully, with no device failure along the follow-up period. Blood loss, operation time, and fluoroscopy time was similar or lower to that reported in the literature for this type of surgeries. Successful fusion was defined as radiographic evidence of bridging trabecular bone between the involved motion segments, as well as translational motion <3mm; and angular motion <5°. Two patients were lost to follow-up. Of the 28 patients, 27 (96.4%) presented with fusion at 12 months. VAS for back pain, leg pain, as well as Oswestry scores and SF-12 were reduced compared to the base line. These values compares favorably to data provided in the literature. In all cases that underwent post-operative CT/MRI, unobstructed imaging clearly demonstrated the patient anatomic structures and/or underlying pathology, with almost no artifacts.

**Conclusion:** This Carbon Fibers Pedicle Screw System compare favorably to the literature, showing high fusion rates, quality of life improvement and safety. As in addition, it allows excellent MRI/CT visibility of the implanted area, with no artifacts. In case of spinal tumor patients, the system enables excellent, interference free imaging, as well as effective radiation therapy with no backscatters.

1. Spine Unit, Meir Medical Center, Kfar-Saba
2. Department of Orthopedics B., Hillel-Yaffee Medical Center, Hadera