Carbon fiber–reinforced PEEK instrumentation in the spinal oncology population: a retrospective series demonstrating technique, feasibility, and clinical outcomes

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OBJECTIVE The authors aimed to demonstrate the feasibility and advantages of carbon fiber–reinforced PEEK (CFRP) composite implants in patients with both primary and secondary osseous spinal tumors.

METHODS Twenty-eight spinal tumor patients who underwent fixation with CFRP hardware were retrospectively identified in a Spine Tumor Quality Database at a single institution. Demographic, procedural, and follow-up data were retrospectively collected.

RESULTS The study population included 14 females and 14 males with a mean age of 60 years (range 30–86 years). Five patients had primary bone tumors, and the remaining patients had metastatic tumors. Breast cancer was the most common metastatic tumor. The most common presenting symptom was axial spine pain (25 patients, 89%), and the most common Spine Instability Neoplastic Score was 7 (range 6–14). Two patients in this series had anterior cervical procedures. The remaining patients underwent posterior thoracolumbar fixation. The average fusion length included 4.6 vertebral segments (range 3–8). The mean clinical follow-up time with surgical or oncology teams was 6.5 months (range 1–23 months), and the mean interval for last follow-up imaging (CT or MRI) was 6.5 months (range 1–22 months). Eighteen patients received postoperative radiation at the authors' institution (16 with photon therapy, 2 with proton therapy). Eleven of the patients (39%) in this series died. At the last clinical follow-up, 26 patients (93%) had stable or improved neurological function compared with their preoperative status. At the last imaging follow-up, local disease control was observed in 25 patients (89%). Two patients required reoperation in the immediate postoperative period, one for surgical site infection and the other for compressive epidural hematoma. One patient was noted to have lucencies around the most cephalad screws 3 months after surgery. No hardware fracture or malfunction occurred intraoperatively. No patients required delayed surgery for hardware loosening, fracture, or other failure. Early tumor recurrence was detected in 3 patients. Early detection was attributed to the imaging characteristics of the CFRP hardware.

CONCLUSIONS CFRP spinal implants appear to be safe and comparable to conventional titanium implants in terms of functionality. The imaging characteristics of CFRP hardware facilitate radiation planning and assessment of surveillance imaging. CFRP hardware may enhance safety and efficacy, particularly with particle therapy dosimetry. Larger patient populations with longer-term follow-up are needed to confirm the various valuable aspects of CFRP spinal implants.

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KEYWORDS carbon fiber screws; carbon fiber–reinforced PEEK; radiotherapy; scattering effect; spinal metastases; separation surgery; spinal oncology; neurooncology

SPINAL metastases are a major burden for oncological care, as they will affect 30%–40% of patients with cancer.¹ Primary bone tumors of the spine are far less common than metastatic spinal tumors, but their behavior can also be aggressive and malignant.² Management of metastatic tumors and primary tumors involving the spine must be individualized. Factors such as tumor histology, radiosensitivity, tumor location, presenting

symptoms, neurological status, and prior surgery, or adjuvant treatment at the diseased level, impact treatment strategy. Surgical intervention may be needed for oncological cytoreduction, histological diagnosis, treatment of mechanical pain, decompression of the neural elements, or correction of instability and/or deformity.

Radiation therapy (RT) is often administered as a definitive or adjuvant therapy during spinal tumor treat-

ABBREVIATIONS CFRP = carbon fiber–reinforced PEEK; PBRT = proton-beam RT; RT = radiation therapy; SINS = Spine Instability Neoplastic Score.

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ment. In patients with limited oligometastatic or epidural spinal cord compression from metastatic spine disease, combined surgery and RT is an established practice. With primary bone tumors, the combination of surgery and RT can be considered for high-grade malignancies, recurrent tumors, or in cases in which satisfactory oncological margins cannot be achieved.³

When surgical intervention in the spinal oncology population requires stabilization with spinal hardware, conventional implant materials can be problematic. Commonly used metallic implant materials such as titanium alloys produce substantial artifacts on imaging that interfere with proper planning and delivery of RT. The presence of metals with a high number of atomic protons in the nucleus (high-Z materials), such as titanium or cobalt, can cause severe artifacts on CT images, which can have a significant impact on radiation dose calculation.⁴ Furthermore, the scattering effect from titanium hardware can compromise the therapeutic effect of RT and lead to unwanted irradiation of neighboring healthy tissues, particularly when particles are used.^{3,5,6} Artifacts from metallic implants also interfere with postoperative surveillance imaging, which are used to rule out disease progression.^{3,7}

Recently, carbon fiber–reinforced PEEK (CFRP) composite implants have garnered attention as an alternative to conventional titanium implants for spinal oncology patients. Previously, numerous clinical papers in the orthopedic literature have described the utility of CFRP implants in nonspinal orthopedic trauma procedures.^{8–10} Those reports cited several beneficial characteristics of CFRP, including biocompatibility and durability.

In the spine, screws, rods, plates, and vertebral body replacement CFRP implants have been described for use in the cervical, thoracic, and lumbar spine segments.^{3,5,6,11–13} Authors have previously highlighted the advantages of CFRP over titanium systems, including reduced amounts of imaging artifacts, more facile RT planning, and potentially greater safety and quality of radiotherapy.^{3,5,6}

However, the number of clinical papers on CFRP remains limited, and to our knowledge no clinical series has described greater than 40 patients stabilized with CFRP instrumentation. The aim of this paper is to describe an additional clinical series, highlighting feasibility and clinical outcomes. An illustrative case demonstrates the advantages of CFRP implants. Technical nuances to one of the currently available CFRP systems, CarboClear (CarboFix Orthopedics Ltd.), are also discussed.

Methods

The study was conducted at a single, tertiary, academic medical center in Phoenix, Arizona. Approval from the Institutional Review Board was obtained.

Starting in December 2018, spinal surgeons considered using CFRP hardware in all spinal oncology patients undergoing instrumented fusions. The treatment teams were also anticipating postoperative radiation treatment or ongoing imaging surveillance in patients treated with CFRP hardware. Because the precontoured rods in the CFRP system cannot be bent, patients with constructs needing custom intraoperative rod contouring were excluded. Pa-

tients needing hardware not currently available in CFRP, such as occipital plates, were also excluded.

Twenty-eight patients who had undergone instrumentation with the CFRP fixation system CarboClear from December 2018 to October 2020 were retrospectively identified in our Spine Tumor Quality Database.

Clinical data were retrospectively collected, including age, sex, tumor pathology, preoperative symptoms, Spine Instability Neoplastic Score (SINS), surgical procedure, date of surgery, presence of intraoperative or postoperative surgical complications, length of clinical and radiographic follow-up, type of radiation treatment, preservation of neurological status during clinical follow-up period, local control, and patient survival. Data are presented with descriptive statistics (Table 1).

Intraoperative neuromonitoring was used during all procedures. Spinal fixation was associated with tumor resection and vertebral column reconstruction using PEEK cages in 5 patients and decompression with tumor debulking in the remaining 23 patients.

All patients were managed collaboratively by surgical and oncology teams. The standard follow-up routine for the surgeons' team included clinical and radiographic follow-up at 3, 6, and 12 months, and yearly thereafter, in order to assess hardware stability and local recurrence.

Surgical Technique

Unlike standard titanium alloy spinal implant systems, insertion of the fully CFRP pedicle screw system involves technical nuances for planning, insertion, and stabilization. First, the selection of pedicle screw starting points must be meticulous to ensure that the final positions of the pedicle screw tulip heads are well aligned. The pedicle screws are polyaxial with 15° of rotation at the center, allowing for a small amount of deviation in screw alignment. The carbon-based microfiber manufacturing of the rods allows for highly cycle-resistant rods but makes for a more challenging fixation to the pedicle screws given the inability to bend the rods. There are multiple different precurved rods available, which can be selected preoperatively based on the curvature of the spine and cut intraoperatively to appropriate length. Well-aligned pedicle screws allow the tulip heads to capture the rod with locking elements. A top-loading press-fitting device functions as a final locking mechanism, akin to final tightening end-caps with titanium alloy systems.

Pedicle placement is performed using standard free-hand direct or anatomical trajectories. Given the closer modulus of the instrumentation to bone, full-length tapping into the vertebral body is needed to allow for appropriate screw placement. The quality of the bone involved also determines the tapping strategy. In osteoblastic bone—seen with metastatic prostate and other specific metastases—tapping to screw diameter for the full length of the screw is recommended. Otherwise, a half-size smaller tap is often used, again to full length, to help facilitate screw placement.

Placement is often confirmed with intraoperative CT imaging, given the near full lucency of the hardware on radiographs; in the lumbar spine, the spinal titanium reinforced shell is often visible, which may obviate the need

TABLE 1. Demographic and clinical data

	Value
Sex	
Male	14
Female	14
Mean age (range), yrs	60 (30–86)
Metastases: tumor histology	
Breast	8
Multiple myeloma	2
Lung	3
Pancreas	2
Prostate	2
Bile duct	1
Cervical	1
Colon	1
Melanoma	1
Thyroid	1
Adenoma, unknown origin	1
Primary bone tumors: tumor histology	
Chondrosarcoma	3
Ewing sarcoma	2
Presenting symptoms	
Axial spine pain	25
Myelopathy	12
Radiculopathy	8
Most common SINS (range)	7 (6–14)
Procedure location	
Cervical	2
Thoracic	19
Thoracolumbar	4
Lumbar or lumbosacral	3
Mean clinical follow-up time (range), mos	6.5 (1–23)
Mean radiographic follow-up time (range), mos	6.5 (1–22)
Preservation of neurological status	26
Local tumor control	25
Survival	17

Values represent the number of patients unless stated otherwise.

FIG. 1. Sagittal T1-weighted contrast-enhanced MR image demonstrating chondrosarcoma involving the T4 vertebral body and posterior elements.

After consultation with the radiation oncology department at our institution, proton-beam RT (PBRT) was recommended to deliver high-dose radiation while minimizing exposure to surrounding tissues, in particular the spinal cord and esophagus. To maximize the safety and efficacy of the PBRT, resection of residual tumor and replacement of the titanium hardware with CFRP hardware were recommended. The patient recovered well from surgery, and our radiation oncology team proceeded with adjuvant curative-intent postoperative PBRT. Her simulation CT is demonstrated in Fig 2. Nineteen months after surgery, follow-up imaging revealed no signs of residual or recurrent disease (Figs. 3–5). CT allows for excellent evaluation of the hardware integrity and loosening at the bone-screw interface, while MRI allows for detection of tumor mass and assessment of surrounding tissues.

Results

The study population included 14 females and 14 males with a mean age of 60 years (range 30–86 years). All patients had a preoperative histological diagnosis. Five patients had primary bone tumors and the remaining patients had metastatic tumors. Breast cancer was the most common metastatic tumor.

Patients often presented with multiple symptoms. The most common presenting symptom was axial spine pain (25 patients, 89%), followed by myelopathy (12 patients, 43%) and radiculopathy (8 patients, 29%). One patient was asymptomatic, but she had radiographic progression of disease. The most common SINS was 7 (range 6–14) of indeterminate stability.

Two patients in this series had anterior cervical procedures. The remaining patients underwent posterior thora-

for high-definition imaging. At this time, no systems exist to coordinate CFRP pedicle screws with an image-guidance platform, although pedicle probing and tapping can be performed with image-guided systems.

Illustrative Case

A 43-year-old woman presented to an outside institution 6 weeks prior with progressive thoracic myelopathy and severe thoracic pain. She was found to have a dorsal T4 mass with destruction of the posterior elements and extension to the ribs and T4 vertebral body (Fig. 1). She was taken urgently for a posterior thoracic subtotal tumor resection and stabilization using titanium hardware. Tumor pathology was consistent with grade 2 chondrosarcoma.

FIG. 2. Simulation CT scans for PBRT.

columbar fixation. Nineteen patients had fixation within the thoracic spine, 4 patients had fixation spanning the thoracolumbar spine, and 3 patients had lumbar or lumbosacral fixation. The average fusion length included 4.6 vertebral segments (range 3–8).

The mean clinical follow-up time with the surgical or oncology team at our institution was 6.5 months (range 1–23 months), and the mean interval for the last follow-up imaging study (CT or MRI) was 6.5 months (range 1–22

months). Eighteen patients received postoperative RT at our institution (16 with photon therapy, 2 with PBRT). Fourteen of the 16 patients treated with photon therapy received stereotactic body RT. Of the 10 patients who had not been treated with RT at the time of submission of this paper, 2 patients were pending radiation treatment, 4 patients chose alternative adjuvant treatments, 3 patients did not thrive, and 1 patient was lost to follow-up.

FIG. 3. Postoperative sagittal thoracic CT scan demonstrating minimal artifact surrounding the CFRP pedicle screw.

FIG. 4. Postoperative sagittal thoracic T2-weighted MR image demonstrating minimal artifact surrounding the CFRP hardware.

FIG. 5. Postoperative axial thoracic T2-weighted MR image demonstrating minimal artifact surrounding the CFRP hardware.

Eleven of the patients (39%) in this series have subsequently died of their primary disease or a complication. At the last clinical follow-up, 26 patients (93%) had stable or improved neurological function compared with their preoperative status. At the last imaging follow-up, local disease control was observed in 25 patients (89%). Results are presented in Table 1.

Two patients required reoperation in the immediate postoperative period, one for surgical site infection and the other for epidural hematoma. One patient was noted to have lucencies around the most cephalad screws 3 months after surgery. The screws were implanted in a diseased vertebral body, and the patient's condition was managed expectantly. No hardware fracture or malfunction occurred intraoperatively. No patients required delayed surgery for hardware loosening, fracture, or other failure. Of the 5 patients with primary bone tumors, 3 patients demonstrated arthrodesis on postoperative CT imaging. The other 2 patients had had surgery more recently and were scheduled to have future CT imaging to assess arthrodesis.

Early tumor recurrence was detected in 3 patients, which may have been facilitated by favorable imaging characteristics of CFRP hardware. In the 3 patients with early tumor recurrence, 2 patients had metastases and 1 patient had a primary tumor. The recurrences were detected at 4, 4.2, and 7 months. One patient with metastasis had palliative RT, and the other patient chose hospice care. The elderly patient with the primary tumor was scheduled for revision surgery. While awaiting surgery, he had unexpected cardiac arrest and died.

Discussion

Surgical management of spinal tumors often requires instrumentation to restore spinal stability and prevent ky-

phosis after neural decompression.¹⁴ In this population, CFRP hardware has been introduced as an alternative to conventional titanium hardware. A small body of evidence demonstrates the viability and benefits of CFRP spinal implant material.

Radiographic Advantages of CFRP Hardware

Multiple studies have shown the clear radiographic advantage of CFRP over titanium hardware on postinstrumentation spinal imaging.^{15–17} In vitro evaluations have shown reduced total artifact volume and median artifact area on MRI scans for CFRP intervertebral test spacers compared with titanium spacers.^{15,18} Another in vitro study found that a CFRP rod-and-screw phantom substantially reduced the susceptibility to artifacts on both CT and MRI compared with a titanium phantom.¹⁹ Fleege et al.²⁰ compared the accessibility of the spinal canal, the neuroforamina, and the surrounding bony and soft-tissue structures after the lumbar spine was instrumented in patients with titanium and CFRP hardware. The authors concluded that the CFRP pedicle screws exhibited smaller artifact areas on vertebral body surfaces and their surrounding tissues, which improved the radiographic assessability.²⁰

The radiolucency and reduced artifact occurrence with CFRP hardware allow for much better interpretation of follow-up imaging. Consequently, more precise radiation planning²¹ and more sensitive surveillance for tumor progression or recurrence are possible.³ Early detection of tumor progression was possible for several patients in this series.

Biomechanical Properties of CFRP Hardware

Testing has shown favorable biomechanical properties for CFRP hardware. CFRP rods have been shown to have mechanical properties, including mean bending yield load, bending ultimate load, cycling capacity, and stiffness that are comparable to commercially available titanium systems.^{22,23}

In osteoporotic human spine cadaver models, CFRP rod-and-screw constructs demonstrated similar²⁴ or less²⁵ microscopic loosening than titanium constructs after cyclic loading tests.²⁵ Cement augmentation significantly enhanced anchorage of the CFRP screws.²⁴

Our experience demonstrated favorable biomechanical properties for CFRP hardware, as no hardware fractures occurred at the rod or screw-rod interfaces. We had only 1 case with hardware loosening, which was primarily attributed to a diseased spinal segment with poor bone integrity.

Clinical Series Demonstrating Feasibility of CFRP Hardware

A limited number of clinical papers have been published describing the safety and noninferiority of CFRP compared with titanium hardware. Cofano et al.¹¹ retrospectively compared the safety and effectiveness of CFRP devices with standard titanium implants in patients with spinal metastases. Thirty-six patients underwent CFRP fixation, while titanium implants were used for 42. No significant differences were found between the two groups

in terms of postoperative clinical complications and hardware-related complications.¹¹

In another clinical series with 34 patients who had a total of 232 CFRP pedicle screws inserted, only 1 intraoperative complication occurred: a screw fractured during insertion. In the cohort, the authors also noted loosening of 2 sacral screws at 9 and 12 months in multilevel revision spine fusion cases. The authors also attributed early detection of 6 local recurrences to implant radiolucency.³

In a third series, Boriani et al.⁶ described 6 cervical cases where a hybrid system made of carbon rods and screws coupled with subliminal polyester bands with titanium clamps was used to stabilize the cervical and cervicothoracic regions. No intraoperative complications were noted, and postoperative RT was administered without alteration in planning.⁶

The findings in this study also demonstrate the safety and feasibility of CFRP hardware, which has been shown in a limited number of previous studies.

Advantages of CFRP Hardware With Radiotherapy

There are many potential advantages of CFRP hardware with RT planning, including improved imaging, which allows for better target and normal tissue delineation. Particularly for lesions involving the spine, identification of the spinal cord is critical, as it represents the primary dose-limiting structure. Tumors requiring high radiation doses for local control, such as chondrosarcoma, chordoma, or those treated with ablative doses of stereotactic body radiation, require precise tumor and normal tissue delineation. In these cases, CFRP hardware is advantageous. In addition to imaging, there are radiation dose calculation advantages. Charged particle radiation such as proton-beam therapy and carbon ion radiotherapy are sensitive to high-Z materials where dose calculation can be affected, and the presence of titanium hardware may increase the risk of local recurrence.⁴ Thus, CFRP is preferred over titanium for these indications.

Numerous studies have demonstrated the benefits of CFRP hardware for postoperative RT. Using simulations and retrospective analysis of real spinal oncology cases, Mastella et al.²⁶ assessed the dosimetry of postoperative particle therapy between patients stabilized with titanium versus CFRP hardware. They found that CFRP hardware, compared with titanium hardware, had very slight beam perturbation, which led to a lower degree of dose degradation.²⁶ Other photon therapy simulations have also found that CFRP systems result in superior dosimetric quality compared with titanium systems.^{21,27}

In another simulation study involving a 6-MV photon beam, investigators found that the maximum dose perturbation was less than 5% for CFRP screws, compared with more than 30% perturbation for the titanium screws.²⁸

Limitations

This is a retrospective review, and data collection was limited to availability in the electronic medical record. For many patients, our facility is a destination medical center. A proportion of patients sought postoperative oncology care at different facilities and medical records were not accessible. Rates of local recurrence and neurological de-

terioration may be higher if all patients completed follow-up care at our facility.

Furthermore, this study did not include standardized pain scores. Therefore, we are not able to quantify improvement in pain or compare pain levels of patients treated with titanium hardware, which has different mechanical properties. We plan to address this question with future prospective studies.

The study included a relatively small number of patients with limited mean clinical and radiographic follow-up intervals. A larger patient cohort with extended follow-up would enhance our understanding of perioperative and postoperative complications. Also, the high mortality rate (39%) in this series raises the question about the survival benefit with CFRP hardware. Longer-term studies with more patients will clarify the impact of CFRP hardware on quality of oncological care, determined by complications, survival, and other patient-reported outcome measures.

Conclusions

CFRP spinal implants appear to be safe and comparable to conventional titanium implants, in terms of functionality. The superior imaging characteristics of CFRP hardware facilitate radiation planning and assessment of surveillance imaging. CFRP hardware may enhance safety and efficacy, particularly with particle therapy. Larger patient populations with longer-term follow-up are needed to manifest the value of CFRP spinal implants.

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Disclosures

Dr. Neal: consultant for Medtronic. Dr. Kalani: consultant for CarboFix, NuVasive, and Medtronic.

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Conception and design: Neal, Ashman. Acquisition of data: Neal, Richards, Patel, Ashman, Vora, Kalani. Analysis and interpretation of data: Neal, Ashman, Vora, Kalani. Drafting the article: Neal. Critically revising the article: all authors. Reviewed submitted version of manuscript: all authors. Statistical analysis: Neal. Administrative/technical/material support: Neal, Richards, Curley, Patel. Study supervision: Neal.

Supplemental Information

Videos

Video Abstract. <https://vimeo.com/525067554>.

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