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Clinical Studies

Attitudes and trends in the use of radiolucent spinal implants: A survey of the North American Spine Society section of spinal oncology

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ABSTRACT

Background: In spinal oncology, titanium implants pose several challenges including artifact on advanced imaging and therapeutic radiation perturbation. To mitigate these effects, there has been increased interest in radiolucent carbon fiber (CF) and CF-reinforced polyetheretherketone (CFR-PEEK) implants as an alternative for spinal reconstruction. This study surveyed the members of the North American Spine Society (NASS) section of Spinal Oncology to query their perspectives regarding the clinical utility, current practice patterns, and recommended future directions of radiolucent spinal implants.

Methods: In February 2021, an anonymous survey was administered to the physicians of the NASS section of Spinal Oncology. Participation in the survey was optional. The survey contained 38 items including demographic questions as well as multiple-choice, yes/no questions, Likert rating scales, and short free-text responses pertaining to the "clinical concept", "efficacy", "problems/complications", "practice pattern", and "future directions" of radiolucent spinal implants.

Results: Fifteen responses were received (71.4% response rate). Six of the participants (40%) were neurosurgeons, eight (53.3%) were orthopedic surgeons, and one was a spinal radiation oncologist. Overall, there were mixed opinions among the specialists. While several believed that radiolucent spinal implants provide substantial benefits for the detection of disease recurrence and radiation therapy options, others remained less convinced. Ongoing concerns included high costs, low availability, limited cervical and percutaneous options, and suboptimal screw and rod designs. As such, participants estimated that they currently utilize these implants for 27.3% of anterior and 14.7% of all posterior reconstructions after tumor resection.

Conclusion: A survey of the NASS section of Spinal Oncology found a lack of consensus with regards to the imaging and radiation benefits, and several ongoing concerns about currently available options. Therefore, routine utilization of these implants for anterior and posterior spinal reconstructions remains low. Future investigations are warranted to practically validate these devices' theoretical risks and benefits.

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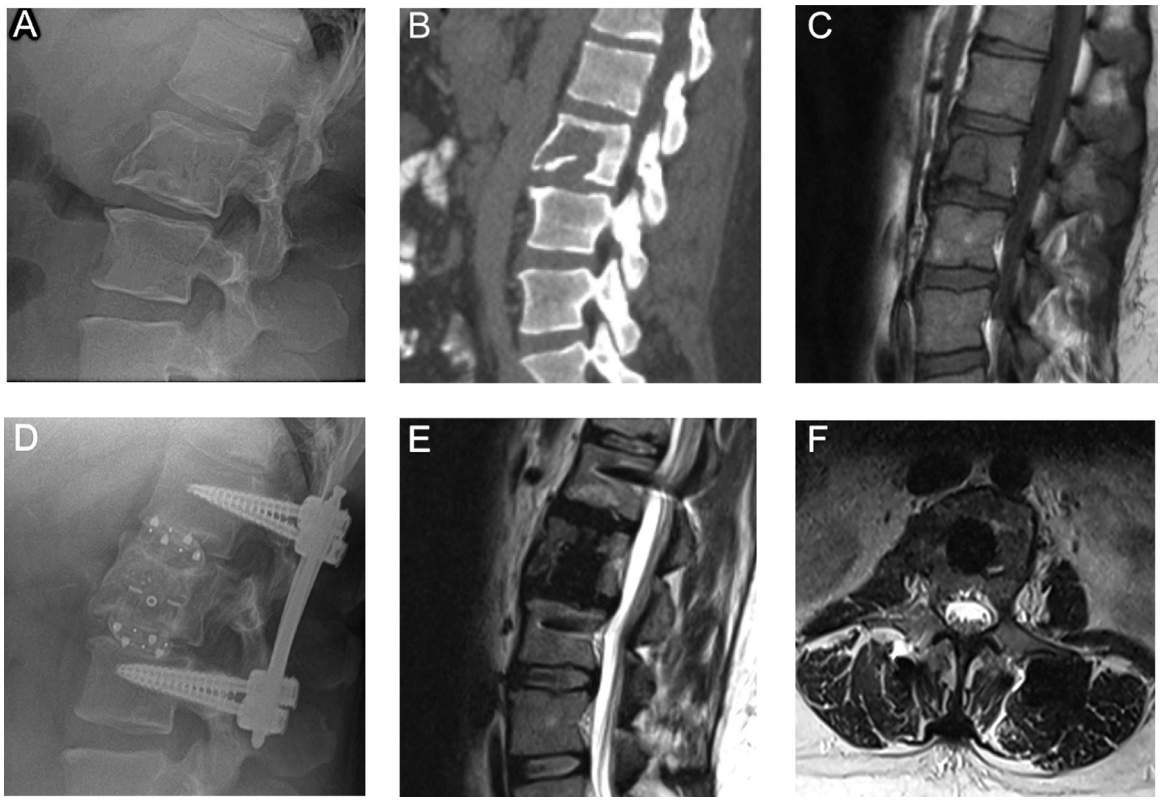

Fig. 1. Preoperative (A) lateral radiograph, (B) sagittal CT, and (C) sagittal T2 MRI demonstrating a lytic lesion in the L2 vertebral body with pathologic fracture consistent with fibrous dysplasia. (D) Lateral radiograph 12 months postoperatively following L1 to L3 posterior instrumented fusion and L2 lateral extracavitary corpectomy with reconstruction using a carbon fiber radiolucent corpectomy cage. (E) Sagittal and (F) axial T2 MRI 5 months postoperatively demonstrating minimal artifact.

Introduction

With the recent advances in surgical options, radiation therapies, and chemotherapeutic options available for the treatment of primary and metastatic spinal lesions, treatment algorithms have evolved and now emphasize greater multidisciplinary collaboration [1,2]. Surgical intervention for resection and subsequent reconstruction is one such modality often used in patients with signs and symptoms of instability, mechanical pain, or neurological deficits [3,4]. Traditionally, reconstruction has been performed with the use of titanium instrumentation due to its reliable strength, stiffness, and ease of use given ubiquity throughout most facets of spine surgery. In the context of spinal oncology, however, titanium implants pose several challenges. Specifically, these implants impart significant artifact on advanced imaging modalities, thus decreasing the reliability of postoperative surveillance for disease recurrence or progression [5,6]. Furthermore, due to its higher density and significant compositional differences from cortical bone, titanium produces perturbation effects which may influence the dosimetry of adjuvant radiation therapies, in addition to complicating target delineation due artifact [7].

Recent years have seen increased interest in carbon fiber (CF) and CF reinforced (CFR) polyetheretherketone (PEEK) spinal implants (**Fig. 1**). Unlike titanium, CF and CFR-PEEK does not impede imaging or perturb radiation, improving the accuracy of dosing and delivery [8–10]. Furthermore, these radiolucent implants have a modulus of elasticity closer to that of compact cortical bone, decreasing the stress at the implant-host bone interface [6,11]. This is especially important among patients with osteoporotic or diseased bone as it decreases the risk for subsequent implant-related mechanical complications such as subsidence, loosening, and fracture [11,12]. However, the current literature on CF and CFR-PEEK radiolucent implants is sparse for both biomechanical and clinical studies, and these implants have their own set of disadvantages. For example, lower tensile strength may contribute to failure with compressive and shear forces, implant failure is difficult to assess, and the implant options available remain limited [13,14].

Given the limited data that currently exists pertaining to these radiolucent implants, this study sought to query the perspectives of the specialists in the North American Spine Society (NASS) section of Spinal Oncology with regards to their clinical utility, current practice patterns, and recommended future directions. Given the lack of data in the literature, our *a priori* hypothesis was that opinions wouldl vary widely even among these specialists.

Methods

This investigation was approved as exempt research by Rush University Medical Center's Institutional Review Board. In February of 2021, an anonymous survey was administered to the 21 physicians in the NASS section of Spinal Oncology via REDCap, an encrypted online database. Participants were spinal oncologists from various disciplines, including Neurological surgery, Orthopaedic surgery, and Radiation Oncology. Participation in the survey was optional.

The survey contained 38 items including demographic questions as well as multiple-choice, yes or no questions, rating scales, and short free-text responses pertaining to the "clinical concept", "efficacy", "problems/complications", "practice pattern", and "future directions" of ra-

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Table 1
Summary of survey responses.

Question	Response Mean (range)
Clinical Concept	
1 Importance of radiolucent implants in optimizing:	
Ability to obtain postoperative MRI/CT imaging for early recurrence detection	6.5 (1-10)
Ability to use photons (SBRT, IMRT) without perturbation	5.8 (2-9)
Ability to use protons without perturbation	6.3 (0-10)
Other (n = 2)	9.5 (9-10)
1 Importance of radiolucency for ANTERIOR column reconstruction	7.0 (2-10)
1 Importance of radiolucency in the following for POSTERIOR column reconstruction	
Rods	5.6 (2-10)
Screws	6.3 (2-10)
1 Most important radiolucent feature for pedicle screws	
Shank	33.3% (5/15)
Tulip	13.3% (2/15%)
Both	53.3% (8/15)
Efficacy	
1 Quality of the current evidence that radiolucent implants have utility compared to traditional implants?	
Basic science / in vitro	5.1 (2-7)
Clinical outcomes	3.1 (0-7)
1 Have you seen a clinical outcome change in your own practice by using radiolucent implants?	
Imaging quality	46.7% (7/15)
Radiation modality options	26.7% (4/15)
Radiation efficacy	20% (3/15)
Other	0% (0/15)
1 Clinically, do you feel there is a difference between all-PEEK implants and carbon fiber or CF Reinforced implants?	
Strength	60% (9/15)
Radiolucency	13.3% (2/15)
Manufacturability	40% (6/15)
Cost	60% (9/15)
Other	0% (0/15)
Problems and Complications	
1 When implants are radiolucent in comparison to traditional implants, is it difficult to detect:	
Proper positioning	26.7% (4/15)
Migration over time / subsidence	53.3% (8/15)
Haloing / loosening	60% (9/15)
Fracture / failure	80% (12/15)
1 How important are the following concerns/problems regarding radiolucent implants?	
Cost	7.7 (2-10)
Availability	6.7 (1-10)
Yield Strength	6.2 (1-10)
Mechanical integrity	6.1 (1-10)
“Too stiff” / inability to bend	7.1 (2-10)
Other (n = 2)	8.0 (6-10)

(*continued on next page*)

Table 1 (*continued*)

Question	Response Mean (range)
Practice Pattern	
1 Importance of radiolucent implants in the following settings	
Metastatic Carcinoma	5.3 (1-10)
Primary Spine Malignancy	7.3 (1-10)
Benign Aggressive Spinal Tumors	5.0 (1-9)
1 Has your usage of radiolucent implants changed over the past 5-10 years?	Yes: 40% (6/15)
1 By how much?	
Always used and pattern has not changed	6.7% (1/15)
Rarely use and pattern has not changed	53.3% (8/15)
Never used to but now use sporadically	13.3% (2/15)
Never used to but now use regularly	20.% (3/15)
Never used to but now use exclusively	6.7% (1/15)
1 For spinal tumor cases (all diagnoses) requiring ANTERIOR reconstruction, in what percentage do you currently use a radiolucent strategy?	27.3% (0%-100%)
1 For spinal tumor cases (all diagnoses) requiring POSTERIOR reconstruction, in what percentage do you currently use a radiolucent strategy?	14.7% (0%-90%)
1 Are you hesitant to adopt radiolucent implants for spinal tumors?	Yes: 73.3% (11/15)
Future Directions	
1 Given your current practice, by how much do you expect to increase your use of radiolucent implants in the next 3 years?	34% (0%-80%)

Table 2
Reasons for hesitancy to adopt a radiolucent strategy.

Response
1 For pedicle screws: Cost for routine use in all tumor cases and worry about hardware failure.
1 I have not had trouble treating tumors or detecting recurrence with traditional bone and harms titanium cages with titanium implants. A radiolucent implant is enticing, but not until I am convinced outcomes are better and complications are fewer or equivocal.
1 Cases with underlying deformity and lumbopelvic fixation
1 Quality of implants / mechanical integrity
1 Cost
1 Lack of clinical studies and concern regarding strength of the implants.
1 Personal experience of failures with CF screws involving pull out of the entire system due to progressive kyphosis, deformity, or poor bone.
1 Technically a little more challenging than traditional screw-rod options. No concerns with anterior cages.
1 Cannot bend the rods; Screw pitch is less optimal
1 Cost

diolucent spinal implants. The rating system used a 10-point Likert scale wherein 10 corresponded to the greatest, strongest positive feeling regarding the question and 0 corresponded the least, most negative feeling about the question. Statistical analysis was performed using SPSS version 26.0 (IBM Corporation, Armonk, NY). Descriptive statistics were used to provide sample characteristics. Responses to categorical questions were reported as proportions and absolute counts, while responses to questions with scaled responses were reported as means with ranges.

Results

Demographics

Overall, 15 of the 21 NASS Spinal Oncology section members completed the questionnaire, for a response rate of 71.4%. Six of the participants (40%) were neurosurgeons, 8 (53.3%) were orthopedic surgeons, and 1 was a spinal radiation oncologist. There were 9 institutions represented by the 12 physicians who answered the optional field. The average number of years in practice among participants was 9.2 years (2-16) and oncology constituted 45.3% (20%-80%) of provider's spine practice. The participants' responses to the survey are summarized by **Table 1**.

Clinical concept

With regards to the importance of radiolucent implants, the ability to obtain postoperative MRI/CT imaging for early recurrence detection received an average score of 6.5 (1-10) out of 10, while the ability to use photons and protons without perturbation received an average score of 5.8 (2-9) and 6.3 (0-10), respectively. Two "other" responses were received, including a statement that the radiolucent "rods do not fracture" (9/10) and that radiolucent implants "allow precise visualization of the cord in the context of instrumentation without requiring a CT myelogram" (10/10). The importance of radiolucent spinal implants to anterior column reconstruction received an average score of 7.0 (2-10),

while the importance of rods and screws for posterior column reconstruction received respective scores of 5.6 (2-10) and 6.3 (2-10). When asked which feature of pedicle screws was most importantly radiolucent, 5 (33.3%) said the shank, 2 (13.3%) said the tulip, and 8 (53.3%) said both.

Efficacy

Regarding the efficacy of radiolucent spinal implants, section members rated the quality of current "basic science/*in vitro*" research with an average score of 5.1 (2-7), while current "clinical outcomes" research received a score of 3.1 (0-7). Seven (46.7%) said they had seen imaging quality differences using radiolucent implants in their own practice, 4 (26.7%) had noticed a difference in radiation options, and 3 (20%) had noticed a difference in radiation efficacy. Furthermore, 9 (60%) noted clinical differences in strength between all-PEEK and CF/CFR-PEEK implants, 2 (13.3%) said there were differences in radiolucency, 6 (40%) in manufacturability, and 9 (60%) in implant cost.

Problems and complications

When asked if radiolucent implants pose problems with imaging, 4 section members (26.7%) said they make it difficult to detect proper positioning, 8 (53.3%) said difficulty in detecting migration/subsidence, 9 (60%) said difficulty detecting haloing/loosening, and 12 (80%) said implant fracture/failure is difficult to detect. Additionally, the average level of concern on a scale from 0 (least) to 10 (most) with radiolucent implants with regards to the following was: cost 7.7 (2-10), availability 6.7 (1-10), yield strength 6.2 (1-10), mechanical integrity 6.1 (1-10), and "too stiff"/inability to bend 7.1 (2-10). "Other" concerns included how to revise, extend, compress, distract, and bend (10/10) carbon fiber implants, as well as "technical concerns" with radiolucent implants (6/10).

Practice pattern

On average, section members felt that radiolucent implants are more important in the context of primary spine malignancy (7.3, range: 1-10) than for metastatic carcinoma (5.3, range: 1-10) and benign aggressive spinal tumors (5.0, range: 1-9). Six (40%) said their practice pattern had changed to increase usage over the past 5-10 years, but the majority said that they rarely use radiolucent implants, and their pattern has not changed. For anterior reconstructions, participants on average utilize a radiolucent strategy for 27.3% (0%-100%) of all cases. These implants are currently used even less frequently by participants for posterior reconstructions, reportedly for 14.7% (0%-90%) of cases. Eleven (73.3%) said they are hesitant to adopt a radiolucent strategy. The reasons were provided by 10 participants and are listed in **Table 2**.

Future directions

When asked by how much they anticipated to increase their usage of radiolucent over the next years based on current practice, section members projected an average increase of 34.0% (0%-80%). **Table 3** lists free-text responses pertaining to future directions and advances that the section members would like to see made available for radiolucent implants going forward.

Discussion

Although radiolucent CF and CFR-PEEK spinal implants provide many theoretical benefits that make them an enticing option for spinal oncologists, there is a paucity of long-term clinical data in the literature, and little is known regarding current usage in routine clinical practice. Therefore, this study surveyed the NASS section of Spinal Oncology, finding mixed opinions even among advanced specialists. Specifically, while several participants believed that radiolucent spinal implants provide substantial benefits for the detection of disease recurrence and radiation therapy options, others remained less convinced. Furthermore, several ongoing concerns were noted, such as high costs, low availability, limited options for cervical reconstruction, and suboptimal design and rigidity, making them more difficult to work with than titanium. As such, participants estimated that they only utilize these implants for 27.3% of anterior and 14.7% of all posterior reconstructions.

A limitation of this study is the relatively small sample size of survey participants. Additionally, all the study's participants practice in large, tertiary academic medical institutions, limiting the generalizability of the findings. For example, only a small proportion of the participants currently utilize radiolucent implants routinely, citing high costs and differences in utilization criteria and institutional contracts between implant manufacturing companies as barriers. Therefore, the estimated usage of CF and CFR-PEEK instrumentation may in fact be inflated relative to the overall spinal oncology practice. Additionally, while societies exist for various spinal conditions, there is not a dedicated society focusing on spinal oncology. The NASS spine oncology section can thus help capture the current practice patterns and opinions of surgeons with clinical and academic interest in spinal oncology.

To date, several studies have evaluated the benefits of radiolucent spinal instrumentation on imaging artifact and radiation perturbation. Mastella *et al.* performed an *in vitro* study evaluating the dosimetric impact of CFR-PEEK devices on postoperative particle therapy when compared to titanium [8]. They found that CFR-PEEK screws caused little beam perturbation when compared to titanium screws and therefore a lower degree of dose degradation. The reduced artifacts on CT also improved dose calculation accuracy. Muller *et al.* retrospectively compared CT data on five patients with titanium and five patients with CFR-PEEK screws reinforced with a thin titanium coating and titanium tulips, also comparing the dosimetric impact of both implants for intensity modulated proton (IMPT) and volumetric arc photon therapy (VMAT) [9]. The authors found no difference in dosimetric quality for VMAT plans between implant types. However, CFR-PEEK implants demonstrated benefits for dosing accuracy on IMPT plans. In a series of 35 patients with spinal tumors, Ringel *et al.* demonstrated that posterior instrumentation with CFR-PEEK implants reduced implant-induced artifact when compared to standard titanium alloy and allowed for sufficient assessment of implant position and integrity [15]. The authors concluded that they are valuable and feasible options for patients with spinal tumors where imaging and radiation are crucial for survival outcomes.

A recent systematic review by Takayanagi *et al.* identified fourteen clinical studies in the literature discussing patient outcomes and complication following surgical reconstruction with CF and/or CFR-PEEK instrumentation, most of which were case reports or small series with limited follow-up under two years [16]. While the authors concluded on the imaging and radiation benefits previously discussed, they also noted several drawbacks of these devices identified by the studies, including limited intraoperative visualization, difficulty with rod bending, and substantial costs. In one of the more robust clinical studies, Boriani *et al.* reported the intraoperative, neurological, and survival outcomes of 34 patients with tumors (fourteen metastases, twenty primary tumors) to the thoracic and lumbar spine who had thoracolumbar fixation with CFR-PEEK implants [17]. There was one screw breakage intraoperatively among the 232 implanted screws, and two instances of screw loosening at nine and twelve months in multilevel constructs due to recurrence. Furthermore, six instances of recurrence were detected early, which the authors attributed to implant radiolucency, although they do not provide evidence to support this assertion. Comparing CFR-PEEK implants in 36 patients to standard titanium implants in 42 patients, Cofano *et al.* found no differences in axial pain and neurologic status functional recovery or clinical and hardware-related complication rates [18].

While there is evidence in support of radiolucent implants, there have been no large-scale clinical studies reporting long-term outcomes.

Table 3
Future directions.

	Response
1	Fenestrated augmented screws, Percutaneous options
1	Reliability
1	Posterior cervical fixation, pelvic fixation
1	Dominoes, iliac screws, cervical implants
1	Improved cost
1	Expandability
1	Cost reduction and data to show a benefit that will allow us to negotiate with our institution
1	Strength equal to that of "traditional" implants
1	Better rod options (whether it's bending or further pre-cut options)
1	Long term biomechanical studies
1	Posterior cervical systems (lateral mass, cervical pedicle screws, C1-2, occipital plate), Expandable CF corpectomy cages, percutaneous (MIS) screws for thoraco-lumbar
1	No response provided
1	Cervical implants
1	More rod options with the ability to contour. Better screw design. Easier rod to screw fixation
1	Percutaneous options

As such, many spinal oncologists remain hesitant to adopt the higher costs and intraoperative challenges associated with these devices until equivocal results have been established. Among this study's participants, only 46.7% noted a benefit in imaging quality in clinical practice, while 26.7% and 20% saw advantages in radiation options and efficacy, respectively. However, these numbers may be skewed by the limited use of these implants in clinical practice.

Another common theme across the responses that were received was the lack of options for cervical reconstruction, percutaneous options for minimally invasive surgery, and rod options with the ability to contour. Furthermore, there remains a discrepancy in the availability of radiolucent anterior versus posterior implants. To date, few posterior systems have been approved by the Food and Drug Administration (FDA), likely influencing the rate of utilization. The findings that 73.3% of section members said they are hesitant to adopt a radiolucent strategy with an estimated use of only 14.7% for posterior reconstructions further emphasizes the need for better data on use criteria. For example, it remains unknown whether CF impacts convention radiation therapy or if it is specifically advantageous to postoperative stereotactic body radiation therapy (SBRT) and photon therapy. This would require preoperative planning for which radiation modality would be employed to avoid unnecessary utilization of radiolucent technology and the associated expenses should the patient be admitted to hospice without adjuvant radiation or undergo conventional fractionated radiation.

Although radiolucent implants provide the potential for a paradigm shift in the world of spinal oncology, there remain obstacles impeding their routine implementation. This study has emphasized the current limitations in the usability of these devices, as well as the need for additional large-scale prospective randomized trials comparing radiolucent implants to the current standard-of-care titanium.

Conclusion

This study surveyed the NASS section of Spinal Oncology for opinions on radiolucent CF and CFR-PEEK instrumentation, finding a lack of consensus with regards to the imaging and radiation benefits. Furthermore, several ongoing concerns were noted, such as higher costs, limited cervical and percutaneous options, and suboptimal screw and rod designs, making them more difficult to work with than titanium. Therefore, routine utilization of these implants for anterior and posterior spinal reconstructions remains low. Future large-scale longitudinal investigations are warranted to further delineate the benefits and complication rates associated with these devices.

Declarations of Competing Interests

The authors have no conflicts of interest to declare. All co-authors have seen and agree with the contents of the manuscript.

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Supplementary materials

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