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Clinical performance of implanted devices used in surgical treatment of patients with spinal tumors: a systematic review

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Abstract

Purpose Implanted devices used in metastatic spine tumor surgery (MSTS) include pedicle screws, fixation plates, fixation rods, and interbody devices. A material to be used to fabricate any of these devices should possess an array of properties, which include biocompatibility, no toxicity, bioactivity, low wear rate, low to moderate incidence of artifacts during imaging, tensile strength and modulus that are comparable to those of cortical bone, high fatigue strength/long fatigue life, minimal or no negative impact on radiotherapy (RT) planning and delivery, and high capability for fusion to the contiguous bone. The shortcomings of Ti6Al4V alloy for these applications with respect to these desirable properties are well recognized, opening the field for an investigation about novel biomaterials that could replace the current gold standard. Previously published reviews on this topic have exhibited significant shortcomings in the studies they included, such as a small, heterogenous sample size and the lack of a cost-benefit analysis, extremely useful to understand the practical possibility of applying a novel material on a large scale. Therefore, this review aims to collect information about the clinical performance of these biomaterials from the most recent literature, with the objective of deliberating which could potentially be better than titanium in the future, with particular attention to safety, artifact production and radiotherapy planning interference. The significant promise showed by analyzing the clinical performance of these devices warrants further research through prospective studies with a larger sample size also taking into account each aspect of the production and use of such materials.

Methods The Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) guidelines were used to improve the reporting of the review. The search was performed from March 2022 to September 2023.

Results At the end of the screening process, 20 articles were considered eligible for this study. Polyetheretherketone (PEEK), Carbon-fibre reinforced polyetheretherketone (CFR-PEEK), long carbon fiber reinforced polymer (LCFRP), Polymethylmethacrylate (PMMA), and carbon screw and rods were used in the included studies.

Conclusion CFR-PEEK displays a noninferior safety and efficacy profile to titanium implanted devices. However, it also has other advantages. By decreasing artifact production, it is able to increase detection of local tumor recurrence and decrease radiotherapy dose perturbation, ultimately bettering prognosis for patients necessitating adjuvant

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treatment. Nonetheless, its drawbacks have not been explored fully and still require further investigation in future studies. This does not exclude the fact that CFR-PEEK could be a valid alternative to titanium in the near future.

Keywords Spinal tumors, Metastases, Spine, Radiolucent implanted devices, Radiotherapy, Coated implant

Introduction

The lives of cancer patients are significantly impacted by spine metastases, which often result in severe pain and neurological disability [1]. Over 30% of patients who have received a cancer diagnosis will be affected by metastatic spine tumors [2], with the thoracic spine being the most common localization followed by the lumbar and cervical sections [3, 4]. Statistically, up to 10% of these patients will develop a clinically significant lesion [5]. Four of the major treatment goals for spine tumours are globally applicable to all spine disorders: achieving pain control, restoration or maintenance of neurological function, spinal stability, and improvement in health-related quality of life [6].

Although the treatment of spine metastases remains palliative, the introduction of targeted agents and immunotherapy has significantly improved survival times for patients with metastases from a wide range of tumour histologies. Local treatment for spine tumours needs to provide long-term local control and prioritize an early return to systemic therapy [7]. Radiation therapy and surgery are the main treatment options for spine metastases. However, the most significant overall advancement has been the evolution and integration of spine stereotactic body radiotherapy (SBRT), as its capacity to deliver an adequate adjuvant radiation dose has drastically transformed therapeutic approaches [8]. As supportive evidence, recent findings reported the superiority of surgical treatment in combination with radiotherapy (RT), as opposed to the previously established therapeutical approach combining RT with corticosteroids [9, 10]. Compared to more invasive methods previously used to treat spine metastases, separation surgery and percutaneous vertebral body cement augmentation have been employed and decreased operation-related morbidity [1, 11, 12]. In addition, a further decrease in operation-related morbidity is reported with minimal access surgery using percutaneous and fenestrated pedicle screws [1].

The implant of traditional metal devices could produce heavy metal artifacts in MRI and CT scans [13, 14]. These artifacts could alter the density and compositions of the healthy tissue, causing a perturbation of radiation beams. In general, irradiation through metal implanted devices should be avoided, particularly for RT, where the local control of the disease and the preservation of normal tissue may be compromised by distortion of the dose distributions and range uncertainties [15]. This advice may not always be observed when defining plan geometry, though, if the choice of beam direction is constrained by dose restrictions for the organs at risk or by the lack of a gantry. In addition, imaging artefacts can make it difficult to distinguish between target and normal structures and can reduce dosage calculations' accuracy [15]. In RT, where dose computation is based on Hounsfield Unit to water equivalent path length calibration curve, CT number assignment to tissues within the irradiation volume is a highly critical issue, which can be exacerbated by the presence of artefacts created by implant materials [16].

In Metastatic Spine Tumour Surgery (MSTS), Titanium alloy Ti6Al4V is the gold standard of implant material. Ti6Al4V has replaced stainless steel due to its higher corrosion and fatigue resistance, lower density and lower modulus of elasticity (E) [17]. However, Ti6Al4V has some shortcomings, including a larger E compared to that of cortical bone (respectively 110 GPa vs. 17–21 GPa). Differences in modulus of elasticity are related to a higher risk of fracture of the adjacent segments or risk of subsidence of cage implanted devices [18–21]. Furthermore, Ti6Al4V may be responsible for the diffusion of metal ions to the surrounding tissue, possibly causing metallosis, redox abnormalities and oxidative stress [22]. Moreover, Ti6Al4V causes artifacts in MRI or CT assessment, decreasing the accuracy of post-RT planning [23]. The presence of artifacts with Ti6Al4V could influence the radiotherapy dose interfering with imaging, hindering the contouring of tumours and surrounding organs [15]. Furthermore, identification of tumour relapse on follow-up imaging may be delayed due to scattering [24]. Software algorithms have been developed to overcome the interference of titanium implanted devices with treatment planning but may result in delayed care and overall waste of resources [25].

Implanted devices used in MSTS include pedicle screws, fixation plates, fixation rods, and interbody devices (cages). A material to be used to fabricate any of these devices should possess an array of properties, which include biocompatibility, no toxicity, bioactivity, low wear rate, low to moderate incidence of artifacts during imaging (via, for example, radiography, fluoroscopy, computed tomography (CT), and magnetic resonance imaging (MRI)), tensile strength and modulus that are comparable to those of cortical bone, high fatigue strength/long fatigue life, minimal or no negative impact on RT planning and delivery, and high capability for fusion to the contiguous bone. The shortcomings of Ti6Al4V alloy for these applications with respect to these desirable properties are well recognized, as stated above. As such, in

recent times, other materials, such as polyetheretherketone (PEEK), carbon fiber-reinforced PEEK (CFR-PEEK), nano-sized TiO2-reinforced PEEK, nano-sized hydroxyapatite (HAp)-reinforced PEEK, nano-sized TiO2/HAp/carbon fiber-reinforced PEEK, have been used in conjunction with subtractive manufacturing method(s), such as rolling, forging, and extrusion. Additionally, there are reports of use of some of the aforementioned materials and additive manufacturing (AM), although these still require further investigation [26–29]. Initial studies report that the rigidity and elasticity of 3D-printed PEEK are still similar to that of human bone [30, 31]. Due to the continuous development of new materials and the improvements in 3D printing surfaces, in the last years, several articles have been published on this topic, reflecting the potential interest of the international audience.

PEEK can be used for the reconstruction of vertebral bodies and promotes interbody fusion without decreasing the accuracy of CT, MRI and RT [29, 32]. In addition, this material is bioinert and biocompatible, with a Young's modulus (3.6 GPa) similar to that of bone [18, 33]. Although PEEK has been shown to have a low fusion rate [34], this limit could be increaased by surface modifications using coatings such as hydroxyapatite (HAp). Furthermore, in conditions requiring higher tensile strength while still allowing for proper radiological follow-up and RT planning, CFR-PEEK may be used as an alternative to titanium [35–40]. The latter has shown complication and revision rates of 9.3% and 17.1% respectively [41], thereby representing a safe material for spinal instrumentation in the oncological context. Other reinforcements for PEEK based implant materials, such as TiO2, have been studied. Nano-sized TiO2-reinforced PEEK has been reported to have high thermal stability and antibacterial action against both Gram-positive and Gram-negative bacteria when exposed to simulated body fluid (SBF) [42].

This systematic review provides a detailed analysis of novel radiolucent biomaterials used in spine metastases management compared with Ti6Al4V and investigates their possible role in the context of MSTS. This study aims to collect information about the clinical performance of these biomaterials from the most recent literature, with the objective of deliberating which could potentially be better than titanium in the future, with particular attention to safety, artifact production and radiotherapy planning interference.

Materials and methods

Eligibility criteria and information sources

The Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) guidelines were used to improve the reporting of the review.

The research question was formulated using the PICOS approach: Patient (P); Intervention (I); Comparator (C); Outcome (O), and Study design (S). The present study selects articles that include patients with primary spine tumours and/or metastases (P), treated by standard implanted devices of Ti6Al4V (I), comparing them with patients treated with radiolucent materials (C). The aim was to assess the resistance properties of the materials, the grade of osteointegration, the complications rate and the possible advantages in radiotherapy usage and imaging follow-up. Moreover, the goals included: describing the evolution of novel materials in spinal surgery for tumour management, their properties and limitations as an alternative to Ti6Al4V, the current strategies to optimize their usage, the rate of artifacts and possible advantages in RT protocols (O). For this purpose, randomized controlled trials (RCTs), non-randomized controlled trials (NRCTs), prospective observational studies (POSs), case-series (CS), retrospective clinical studies (RCSs), case reports (CRs) and retrospective cohort studies (RCoSs) were included.

A comprehensive search of Medline, Cochrane, Scopus, CINAHL, and Embase was conducted from the databases' inception to September 2023.

Search strategy

The following keywords were used: "spinal neoplasms", "metastatic spine tumour surgery", "spine surgery", "spine tumours", "spine oncology", "spinal metastases", "spinal neoplasms", "metastatic spine tumour surgery", "spine surgery", "Ti6Al4V", "titanium dioxide,", "implant", "screw", "rods", "system", "polyetheretherketone", "PEEK,", "PAEK", "PMMA", "silicon nitride", "HA coated PEEK", "hydroxyapatite coated", "titanium PEEK", "Ti35Nb4Sn", "carbon", "carbon fiber" "carbon fiber PEEK", "stainless steel", "polyetheretherketone", "hydroxyapatite", "radiolucent", "porosity", "elastic modulus,", "weight-bearing", "corrosion", "rigidity" "fatigue strength", "bioactivity", "intraoperative contouring", "intra-operative cutting", "stress shielding", "osseointegration", "artifacts", "radiotherapy", "magnetic resonance imaging", "computed tomography". Keywords were used both isolated and combined to their Mesh terms. In addition, more studies were searched among the references of the selected papers. The final search string was: ((((((((((spinal neoplasms) OR (metastatic spine tumor surgery)) OR (spine surgery)) OR (spine tumors)) OR (spine oncology)) OR (spinal metastases)) OR (spinal neoplasms)) OR (spine surgery)) AND (((Ti6Al4V) OR (titanium dioxide)) OR ((((implant) OR (screw)) OR (rods)) OR (system)))) AND ((((((((((((((((polyetheretherketone) OR (PEEK)) OR (PAEK)) OR (PMMA)) OR (silicon nitride)) OR (HA coated PEEK)) OR (hydroxyapatite coated)) OR (titanium PEEK)) OR (Ti35Nb4Sn)) OR (carbon)) OR (carbon fiber)) OR (carbon fiber PEEK)) OR (stainless steel)) OR (polyetheretherketone)) OR (hydroxyapatite)) OR

(radiolucent))) AND ((((((radiotherapy) OR (magnetic resonance imaging)) OR (computed tomography)) OR (radiotherapy)) OR (magnetic resonance imaging)) OR (computed tomography)).

Inclusion criteria

Only articles published in English were included, and screening was limited to clinical studies. Articles reporting patients who underwent surgery for primary spinal tumours or metastases were considered. All types of primary tumours were included.

Exclusion criteria

The following exclusion criteria were applied: studies not published in English, technical notes, in vitro, biomechanical, finite elements, animal and cadaver studies.

In addition, papers were discarded if subjects were affected by osteoporotic vertebral fractures, degenerative conditions, rheumatic conditions, infective diseases, and pre-existing vertebral fractures.

Selection process and data collection

The search was performed from March 2022 to September 2023. The initial search of the articles was conducted by two independent authors (GC and GZ) using the previously described search protocol. The chosen research order consisted of screening titles first and abstracts and then full articles. Articles were considered possibly relevant, and their full texts were reviewed if both independent reviewers found they could not be excluded based on their title and abstracts. In case of disagreement, a third reviewer was consulted (SDS). After the full-text assessment, the references of the articles included were screened. Articles were screened using the CADIMA software [43]. The number of articles included or excluded was registered and reported in a PRISMA flowchart. Rules reported by Page et al. were followed in designing the PRISMA chart (*44*).

Data items and synthesis methods

The extracted study characteristics were: author, year, journal, country, type of study and level of evidence (LOE), sample size, mean age, type of tumour, location of the tumour, histology, type of treatment, implant material and proprieties, postoperative radiotherapy, follow-up, local recurrence rate (defined as the number of patients who experienced a recurrence during the study period), fusion rate, complications and possible advantages of new materials. Furthermore, the Visual Analog Scale (VAS), Oswestry Disability Index (ODI) [44] and the American Spinal Cord Injury Association (ASIA) impairment scale values were reported when available.

Categorical data were summarized as frequencies with percentages. However, the data obtained from the studies were too different and heterogeneous to perform a meta-analysis.

Assessment of risk-of-bias studies

The Risk of Bias (RoB 2) tool for randomized trials and The Methodological Index for Non-Randomized Studies (MINORS) were used to assess the quality of the included studies [45, 46]. However, no randomized controlled trials were found. The MINORS score consists of 12 items: clearly stated aim; inclusion of consecutive patients; prospective data collection; endpoints appropriate to study aim; unbiased assessment of study endpoint; follow-up period appropriate to study aim; <5% lost to follow-up; prospective calculation of study size; adequate control group; contemporary groups; baseline equivalence of groups; and adequate statistical analyses [45]. The reviewers individually evaluated all these items. The MINORS items were scored 0 if not reported, 1 when reported but inadequate, and 2 when reported and adequate. The ideal global score was 20 for NRCTs. The simplicity of MINORS comprising only 12 items, makes this item readily usable by both readers and researchers. The reliability of this score has already been documented [45].

Using the MINORS tool, two authors (GC and GZ) independently assessed the potential risk of bias in the selected studies. If no consensus was obtained between the two reviewers, the opinion of a third independent reviewer (SDS) was decisive.

Results

Study selection

Following the PRISMA protocol, a flowchart diagram displaying the study selection process was reported (Fig. 1). Initially, 906 studies were found (studies from grey literature have not contributed to the research, and unpublished studies were not retrieved). 465 studies were from Medline; 213 from Scopus; 184 from Embase, 39 from CINAHL and 5 from Cochrane. A total of 816 studies were maintained following duplicate removal. Of those, 705 were excluded after the title and abstract screening. Of the 111 remaining reports, 3 were not retrieved. Then, 108 full-text articles were extracted. Among these, 88 were excluded: not inherent to our research ($n=60$); no full-text found ($n=28$). At the end of the screening process, 20 articles were considered eligible for this study.

Patients and study characteristics

No RCTs were considered eligible for this study. The selected articles included 20 NRCTs: 13 case-series [21, 24, 47–57], 2 prospective observational studies [35, 58], 2 retrospective cohort studies [59, 60], 2 case reports [37, 61] and 1 retrospective clinical study [62]. The studies ranged from level II to level IV. Studies were published between 2000 [53] and 2021 [50–52, 56, 57]. 823 patients

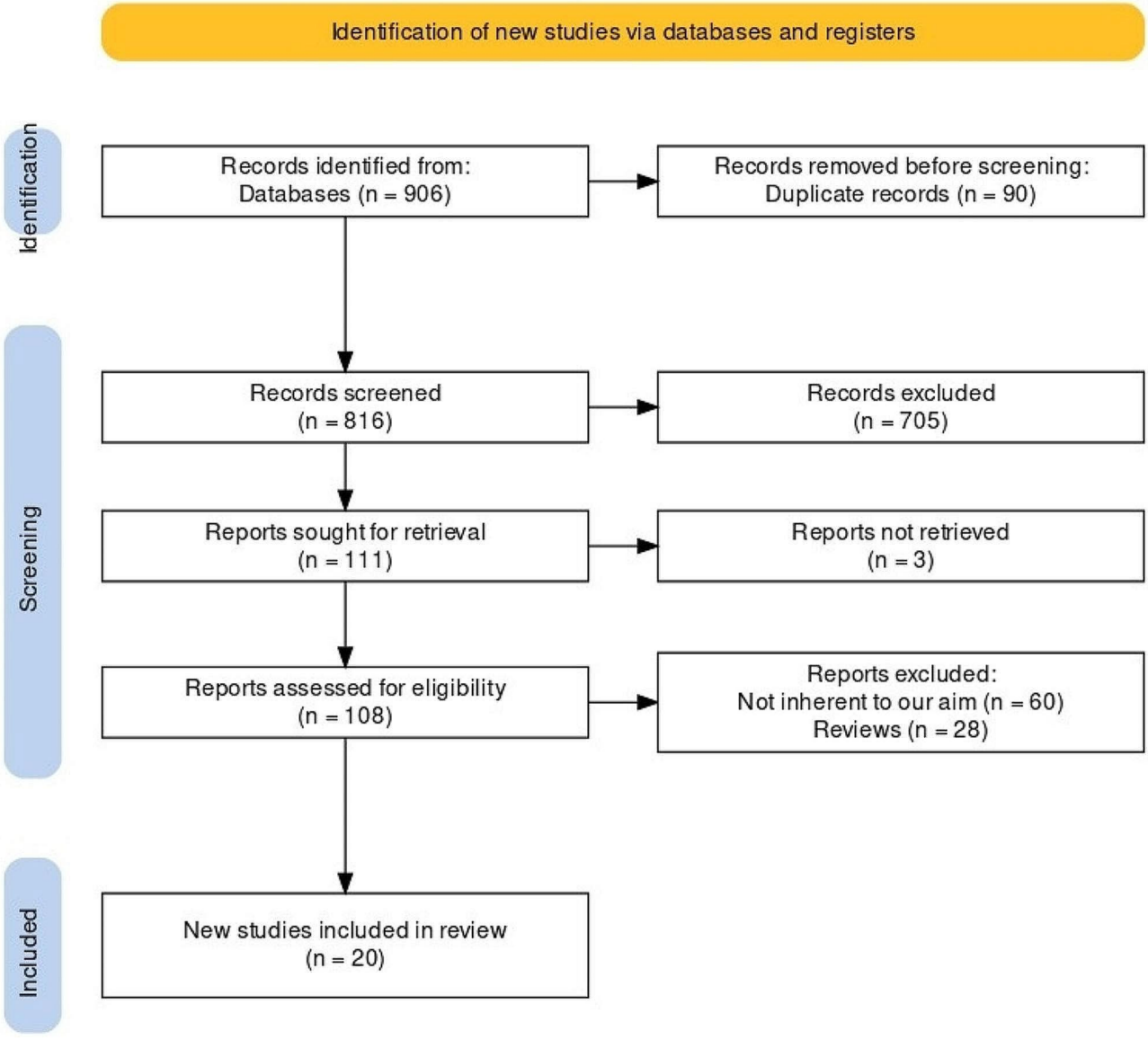

Fig. 1 Prisma flowchart of the included studies

from 41.4 to 86 years were included in this systematic review. The follow-up ranged from 3 to a maximum of 53 months. Thirteen studies (65%) were performed in European countries, three studies in the United States (15%), one study in Japan (5%), one study in China (5%), one study in Korea (5%) and one was a multicentre study (5%). All the characteristics of the patients included were reported in Table 1.

Type of implanted devices

CFR-PEEK was the most frequent material used (15 studies), vertebral augmentation with Polymethylmethacrylate (PMMA) was adopted in 5 studies, metal implanted devices with titanium screws were used in 4 studies, PEEK devices were employed used in 2 studies, long carbon fiber reinforced polymer (LCFRP) was used in 1 study, carbon clamps were reported in 1 study (Table 2).

Type of tumours and type of implanted device

Several authors did not report the incidence of primary or secondary tumors. Among the data reported, 94 patients were affected by metastases; while 49 with primary tumors. RT was used in 6 studies, adjuvant RT for a variety of duration was used in 6 studies, VAS, ODI, and/or ASIA scores were given for each of the studies, incidence of local recurrence was given in 13 studies, and fusion rate was given in only 1 of the studies [59] (Tables 3, 4 and 5).

ASIA scale: Grade A: completed SCI; Grade B: sensory incomplete; Grade C: motor incomplete; Grade D: Motor

Table 1 Patient and study characteristics

Author	Year	Country	Type of study and Level of Evidence (LOE)	Sample size		Age (y)	
				M	F	M	F
Shen, et al.	2022	Multicenter	Retrospective, multicenter cohort study, LOE III	7	6	59.4 ± 8.8	53.8 ± 17.7
Wagner, et al.	2021	Germany	Case series, LOE IV	23	28	-	-
Trungu, et al.	2021	Italy	Case series, LOE IV	8	9	-	-
Neal, et al.	2021	United States	Case series, LOE IV	14	14	-	-
Müther, et al.	2021	Germany	Case series, LOE IV	3	4	43 ± 17.6	40.3 ± 14.9
Cofano, et al.	2020	Italy	Prospective observational study, LOE II	48	30	-	-
				23	13		
				25	17		
Boriani, et al.	2020	Italy	Case series, LOE IV	3	3	-	-
Pipola, et al.	2020	Italy	Case series, LOE IV	1	0	42	-
Sakaura, et al.	2019	Japan	Retrospective cohort study, LOE III	63	65	-	-
				19	17		
				44	48		
Laux, et al.	2018	Switzerland	Case series, LOE IV	1	0	77	-
Boriani, et al.	2018	Italy	Case series, LOE IV	18	16	-	-
Ringel, et al.	2017	Germany	Case series, LOE IV	15	20	61.9 ± 14.1	65 ± 10.1
				7	10	61 ± 16.3	64.6 ± 8.5
				7	10	60.7 ± 12.7	65.3 ± 11.9
				1	0	76	-
Tedesco, et al.	2017	Italy	Case series, LOE IV	18	10	-	-
Tan, et al.	2013	China	Case series, LOE IV	16	12	-	-
Anselmetti, et al.	2013	Italy	Prospective observational study, LOE II	22	18	-	-
Rajpal, et al.	2012	United States	Case series, LOE IV	37	20	-	-
				14	13		
				2	3		
				4	1		
Disch, et al.	2011	Germany	Retrospective clinical study, LOE III	9	11	-	-
Burkett, et al.	2012	United States of America	Case series, LOE IV	20	9	-	-
Jang, et al.	2002	Korea	Case series, LOE IV	5	5	50 ± 18.7	60.4 ± 9.9
Schulte, et al.	2000	Germany	Case series, LOE IV	2	3	56 ± 14.1	54 ± 19.7

incomplete state with a muscle grade of less than three and at least half (or more) of the major muscle functions below the single neurological level of injury; Grade E: normal patient.

Risk of bias in studies

The MINORS tool was used to assess the risk of bias in NRCTs. The computed MINORS scores for the studies found 11 of them [35, 47, 48, 50–53, 55, 56, 59, 62] (55%) had a low risk of bias (total MINORS score ≥ 9), and 9 [21, 24, 37, 49, 54, 57, 58, 60, 61] (45%) had an intermediate risk of bias (total MINORS score < 10) (Table 6).

The MINORS items were scored 0 if not reported, 1 when reported but inadequate, and 2 when reported and adequate. The ideal global score was 20 for NRCTs.

Results of individual studies

Ti6Al4V pedicle screws (gold standard)

One study [35] compared the effectiveness of CFR-PEEK and Ti6Al4V pedicle screws. The results are reported in Tables 3, 4 and 5.

Vertebral augmentation + PMMA

PMMA was employed in five studies [49, 52, 54, 57, 58]. The results are reported in Tables 3, 4 and 5.

Carbon screws + CFR-PEEK

CFR-PEEK was the most used radiolucent material in the studies included. Thirteen studies [24, 35, 47, 48, 50, 51, 53, 55–57, 59, 60, 62] used CFR-PEEK pedicle screws. The results are reported in Tables 3, 4 and 5.

Carbon screws + titanium coated PEEK

Titanium-coated PEEK (Ti-PEEK) was used in two studies [24, 59]. The results are reported in Tables 3, 4 and 5.

Table 2 Type of treatment and tumour characteristics

Author	Year	Type of treatment	Type of tumor	Histology	Location
Shen, et al.	2022	Corpectomy and AR with CFR-PEEK cage + PSD with CFR-PEEK screw-rod system and/or anterior CFR-PEEK plate	Primary (NS)	Chordoma, (8) Metastatic Colon, (1) Metastatic renal cell	L1, (1) T11, (1) T12, (2) L3, (1) L5, (2) L2, (1) T1, (2) T6, (1) T9, (1) T11-12 (1)
			Metastases (NS)	carcinoma, (1) Metastatic breast, (1) Metastatic pancreatic, (1) Melanoma (1)	
Wagner, et al.	2021	PSD	Primary (NS)	Breast, (13) Nonesmall cel lung, (8) Prostate, (7) Unknown primary, (5) Sarcoma, (3) Uterus, (2) Renal cell, (2) Myeloma, (2) Duodenal, (1) Adrenal, (1) Sinus, (1) Oropharynx, (1) Thyroid, (1) Melanoma, (1) Urothelial, (1) Pharynx, (1) Colorectal (1)	Thoracic, (17) Thoracolumbar, (12) Lumbar (22)
Trungu, et al.	2021	Anterior corpectomy and plating with CFR-PEEK	Metastases (NS)	Lung3 (17.6%), Kidney 2 (11.8%), Colon 1 (5.9%), Prostate 5 (29.4%), Breast 6 (35.3%)	C3 1 (5.9%), C4 8 (47.1%), C5 5 (29.4%), C6 2 (11.8%), C7 1 (5.9%)
Müther, et al.	2021	PSD CFR-PEEK	Primary (7)	Hemangiopericytoma, (1) Schwannoma, (5) Cavernous hemangioma (1)	T12-L1, (2) L2-L3, (3) L3-L4 (2)
Neal, et al.	2021	PSD CFR-PEEK	Primary (5) Metastases (23)	Breast, (8) Multiple myeloma, (2) Lung, (3) Pancreas, (2) Prostate, (2) Bile duct, (1) Cervical, (1) Colon, (1) Melanoma, (1) Thyroid, (1) Adenoma (NS), unknown origin, (1) Chondrosarcoma, (3) Ewing sarcoma (2)	Cervical, (2) Thoracic, (19) Thoracolumbar, (4) Lumbar or lumbosacral (3)
Cofano, et al.	2020	PSD for Thoracic or lumbar locations AR for cervical lesions	Primary (NS)	12 Lung NSCLC (33.3%), 6 Mieloma (16.7%), 4 Breast (11.1%), 4 Prostate (11.1%), 3 Renal Cell (8.3%), 3 Colon (8.3%), 2 Melanoma (5.6%), 2 Non-Hodgkin Lymphoma (5.6%)	Cervical 1 (2.9%), Thoracic 30 (83.3%), Lumbar 5 (13.8%)
		PSD		11 Lung NSCLC (26.2%), 7 Mieloma (16.7%), 7 Breast (16.7%), 6 Prostate (14.3%), 4 Melanoma (9.5%),3 Colon (7.1%), 2 Renal Cell (4.7%), 1 Hepatocellular carcinoma (2.4%), 1 Non-Hodgkin Lymphoma (2.4%)	Cervical 2 (4.7%), Thoracic 32 (76.2%), Lumbar 8 (19.1%)
Boriani, et al.	2020	En bloc (2) Intralesional excision (4) + PSD and AR (4) + PSD (2)	Primary (NS)	Epithelioid sclerosing fibrosarcoma, (1) Giant cell tumor, (2) Chordoma, (1) Meningioma, (1) Ewing's sarcoma (1)	C3-C4-C5-C6-C7-T1
Pipola, et al.	2020	PSD	Primary	Sclerosing Epithelioid Fibrosarcoma	C5-C6-C7
Sakaura, et al.	2019	PSD with CBT screw + cages filled with local bone	NS	NS	L1 to L2, (1) L2 to L3, (1) L3 to L4, (19) L4 to L5 (99), L5 to L6, (1) L5 to S1 (7)
Boriani, et al.	2018	PSD (9); PSD + intralesional excision (21); PSD + en bloc resection (4). PSD + AR (15)	Primary (20) Metastases (14)	NS	Thoracic, (5) Thoracolumbar, (19) Lumbar, (2) Lumbo-sacral (8)
Laux, et al.	2018	Dorsal instrumentation and fusion + iliac crest autograft and demineralized bone matrix	Multiple Myeloma	Osteolytic metastasis with vertebral wall involvement	T12
Ringel, et al.	2017	PSD CFR-PEEK	Hematologic malignancies (3)	Breast, (5) Chordoma, (1) Esophageal, (1) Fibrous dysplasia, (1) Gastrointestinal, (2) Hepatocarcinoma, (1) Lymphoma, (2) Melanoma, (2) Myeloma, (1) Prostate, (3) Rectum, (1) Rhabdomyosarc (2)	T10 (3); T11 (3); T2 + 3 (1); T3 (1); T4 (1); T4 + 5 (1); T5 (1); T5 + 6 (2); T6 (1); T6 + 7 + 8 (1); T6 + 8 (1); T7 (1); T7 + 9 + 10 (1); T8 + 12 (1); T8 + 9 (2); T9 (2)
			Primary (2) Metastases (30)		L1 (1); L1 + 2 + 4 (1); L2 (1); L3 (2); L3 + 4 (1); L4 (4); L5 (1)

Table 2 (continued)

Author	Year	Type of treatment	Type of tumor	Histology	Location
Tedesco, et al.	2017	PSD (3) with CFR-PEEK screws + Debulking (15); + en bloc resection (4) AR + CFR-PEEK cage (4) + acrylic cement (5) + titanium cage (2) + allograft (1)	Primary (NS)	Angioma, (1) Hemangioma, (1) Osteoblastoma, (1) Epithelioid hemangioendothelioma, (1) Chordoma, (9) Chondrosarcoma, (2) Myoepithelioma, (1) Myopericytoma, (1) Osteosarcoma, (2) Dedifferentiated liposarcoma, (1) Fibrosarcoma, (1) Ewing sarcoma (1)	Thoracic and lumbar
Tan, et al.	2013	Vertebroplasty with PMMA	Myeloma (9) Metastases (19)	Colon, (2) lung, (8) breast, (7) liver (2)	Thoracic, (10) Lumbar spine (18)
Anselmetti, et al.	2013	PVA + endovertebral devices	Myeloma (9) Metastasis (3)	Osteolytic metastasis with vertebral wall involvement	NS
Rajpal, et al.	2012	AR (13) PSD (14) AR-PSD (10)	Metastases (NS)	NS	Thoracic 23 (61.2%), Lumbar 14 (37.8%)
Burkett, et al.	2012	Anterior cervical corpectomy	Primary (NS)	NS	Cervical (1)
Disch, et al.	2011	Multilevel (2–5 segments) en-bloc	Primary (15) Metastases (5)	Teratoma, (2) Renal cell, (2) Breast, (3) Osteosarcoma (NS), Synovial sarcoma, (4) Chordoma (NS), Osteoblastoma (NS), Giant cell tumor (2) Chondrosarcoma (NS), Neurofibrosarcoma (NS), Solitary plasmocytoma (NS)	Thoracic, (13) Thoracolumbar, (3) lumbar (4)
Jang, et al.	2002	Posterior laminectomy and partial corpectomy. Corpectomy, (1) anterior PMMA-augmented screw fixation with Z-plate	Primary (NS)	Thyroid, (2) Testicular, (1) lung, (1) rectal, (1) metastasis unknown origin, (1) multiple myeloma, (1) breast, (1) urethral, (1) parotid gland (1)	T10–12 (2 T12–L1 (2) T6–8, (1) T1–2, (1) T5–7, (1) T12–L2, (1) T9–L1, (1) T10–L1 (1)
Schulte, et al.	2000	Intralesional excision + discectomy and anterior longitudinal ligament excision	Primary (NS) Metastases (NS)	Breast, (3) Kidney (2)	L1-L4

AR: anterior reconstruction; CBT: cortical bone trajectory; CFR-PEEK: carbon fiber reinforced poly-ether-ether-ketone; NS: not specified; NSCLC: non-small-cell lung cancer; PMMA: polymethylmethacrylate; PVA: Percutaneous vertebral augmentation; PSD: Posterior Stabilization and decompression

PEEK pedicle screws

Only one study [58] used PEEK endovertebral devices without coating or composite material. The results are reported in Tables 3, 4 and 5.

Discussion

This systematic review offers a contemporary assessment of radiolucent biomaterials in spinal surgery, with a particular focus on their attributes and practical implications. The principal finding of this review underscores these materials as potentially dependable solutions for individuals with primary and metastatic spinal lesions. Nonetheless, it's crucial to acknowledge that the field of application of radiolucent implanted devices in metastatic patients remains underexplored. The present review is the only one among recent literature to have performed a qualitative analysis of the included articles, reviewing the most recent literature as well. This study was the one that included the most articles, as an exhaustive literature analysis was carried out. The aim is to underscore the importance of three crucial aspects when deliberating over implanted devices, namely, safety, artifact production, and radiotherapy dose perturbation.

An aspect that is emphasized by numerous publications is the significance of utilizing multiple fields in radiotherapy (RT) to augment dosimetric accuracy, especially when patients possess metal implanted devices [34]. These radiolucent implanted devices were created especially for oncology and they are typically advised for patients eligible for radiation therapy. Treatment plan dosimetric accuracy and robustness can be increased by reducing image artefacts and the contouring

Table 3 Implant properties and radiotherapy management

Author	Year	Implant proprieties	Regimen of RT post-surgery	Follow-up (months)
				Duration of RT post-surgery
Shen, et al.	2022	CFR-PEEK	8	7 ± 5.9
Müther, et al.	2021	CFR-PEEK	NA	9.5
Neal, et al.	2021	CFR-PEEK carboclear	18	6,5
Wagner, et al.	2021	Fenestrated CFR-PEEK pedicle screw system, PMMA	NA	9.8 ± 8.6
Trungu, et al.	2021	CFR-PEEK mesh cage with carbon composite. CFR-PEEK anterior cervical plate	17	12.9 ± 4.0
Cofano, et al.	2020	CFR-PEEK fixation system and Titanium	NA	12,6
Boriani, et al.	2020	Two composite CFR-PEEK rods, polyester (polyethylene-terephthalate) clamps and titanium clamps Thoracic composite CFR-PEEK screws	03-giu	33 ± 4,42
Sakaura, et al.	2019	Titanium-coated PEEK and CFR-PEEK cage	NA	-
Boriani, et al.	2018	CFR-PEEK fixation system	NA	Not specified
Ringel, et al.	2017	CFR-PEEK and Pedicle screws coated with titanium	NA	Not specified
Tedesco, et al.	2017	CFR-PEEK	19	10
Anselmetti, et al.	2013	PMMA PEEK endovertebral devices	NA	10.0 ± 3
Tan, et al.	2013	PMMA	NA	23 (3–44)
Rajpal, et al.	2012	Metal implants, bone implants, and PMMA	NA	21,1
Dish, et al.	2011	LCFRP	NA	25
Jang, et al.	2002	PMMA	NA	7.8 ± 4
Schulte, et al.	2000	CFR-PEEK	3	19.4 ± 14.2

CFR-PEEK: Carbon-fibre reinforced polyetheretherketone; LCFRP: long carbon fiber reinforced polymer; NA: not assessed; PMMA: Polymethylmethacrylate

uncertainties that result and by significantly reducing dose perturbation effects [64].

Most of the reviewed studies have demonstrated favorable outcomes when using PEEK. The mechanical properties of this material, which closely resemble those of cortical bone, facilitate load distribution in the anterior column and reduce stress shielding at the bone-to-screw interface [65]. Moreover, lower artifact volume, imaging scattering, and lower Hounsfield Unit (HU) variation between implanted devices and adjacent tissues [47, 61, 66] may allow operators to allocate their time and resources better during treatment planning.

Composite implanted devices: combining carbon fiber or titanium with PEEK to overcome its limitations

Limitations of PEEK implanted devices include low integration with surrounding tissues due to their bioinertness [67]. Furthermore, they are semi-rigid and do not achieve immediate postoperative spinal stability [68]. Many studies showed that the limitations of PEEK implanted devices can be mitigated by creating composite, surface-coated pedicle screws materials like carbon fiber [47, 55]. CFR-PEEK has been shown to be a reliable composite material, combining the advantages of carbon fiber stiffness while maintaining PEEK's radiolucent properties [56]. Moreover, most included articles have confirmed that CFR-PEEK is able to stimulate osteointegration [24], enhancing the secondary stability of implanted screws. The challenge of intraoperative visualization with non-metal biomaterials has also been addressed. Ringel et al. [24] conducted a study including 35 patients to analyze intraoperative fluoroscopic visualization of vertebral screws. In this context, CFR-PEEK implanted devices were coated with titanium around the pedicle area. This technique has demonstrated efficacy in improving the visualization of screws during surgery. Only one suboptimal placement and one intraoperative screw breakage were recorded due to sclerotic bone due to prostate cancer metastasis. However, using four or more screws still impairs spinal canal visualization on postoperative MRI due to artifact from the titanium screw head.

Additionally, as shown in the study by Sakaura et al. [59], the integration of titanium with PEEK materials can enhance tissue integration and osteoconductivity. Titanium compensates for PEEK's semi-rigidity by strengthening fixation [18]. It is important to note that this study concluded there was no statistically significant difference in patient survival between titanium and CFR-PEEK implanted devices. However, CFR-PEEK devices may be preferable for better postoperative management and follow-up, especially in the context of primary spinal tumors that require precise radiotherapy planning and radiographic monitoring [54, 58]. It has to be noted that this study used a homogenous sample size, with all patients undergoing the same procedure.

Table 4 Outcomes

Author	Year	VAS			ODI			ASIA		
		Pre	Post	*P*-value	Pre	Post	*P*-value	Pre	Post	*P*-value
Schulte, et al.	2000	-	-	-	-	-	-	-	-	-
Jang, et al.	2002	7 ± 1.3	2.3 ± 1.1	0.005*	-	-	-	-	-	-
Disch, et al.	2011	-	-	-	-	-	-	-	-	-
Rajpal, et al.	2012	-	-	-	-	-	-	E: 16 (43%)	All patients either improved or maintained neurologic function at the time of discharge	< 0.05*
Anselmetti, et al.	2013	10 (6–10)	1 (after 1 m, 0–3)	< 0.001*	82.2%	4.1%	< 0.001*	-	-	-
Tan, et al.	2013	8.7 ± 0.95	2.2 ± 1.03	< 0.001*	73.80 ± 5.47	30 ± 5.46	< 0.001	A:0 B:5 C:14 D:9 E:0	All patients had significantly improved neurological function after surgery	< 0.05*
Tedesco, et al.	2017	2.7 ± 2.3 (0–8)	0.3 ± 0.6 (0–2)	-	-	-	-	A:0 B:1 C:3 D:5 E:25	A:0 B:1 C:3 D:5 E:25	-
Ringel, et al.	2017	-	-	-	-	-	-	-	-	-
Boriani, et al.	2018	2.7 ± 2.3	0.3 ± 0.6 (1w)	-	-	-	-	A:0 B:1 C:3 D:5 E:25	A:0 B:1 C:1 D:6 E:26	-
Sakaura, et al.	2019	-	-	-	-	-	-	-	-	-
Boriani, et al.	2020	-	-	-	-	-	-	-	-	-
Cofano, et al.	2020	8.5 1.5/7–10	1.9 1.1/1–3 (last fu)	< 0.01*	-	-	-	A:0 B:0 C:3 D:9 E:24	A:0 B:1 C:0 D:4 E:31	< 0.01*
		8.4 1.4/7–9	2.1 1.0/1–3	< 0.01*	-	-	-	A:0 B:0 C:5 D:15 E:22	A:0 B:1 C:1 D:8 E:32	< 0.01*
Trungu, et al.	2021	NDI. 54.4 (12.2–24.2)	NDI. 3.8 (last fu)	< 0.001*	-	-	-	-	-	< 0.001*
Neal, et al.	2021	-	-	-	-	-	-	-	-	-
Müther, et al.	2021	-	-	-	-	-	-	-	-	-
Shen, et al.	2022	-	-	-	-	-	-	A:0 B:1 C:1 D:0 E:11	A:0 B:0 C:0 D:3 E:10	-

ODI: Oswestry Disability Index; VAS: visual analogue scale; *: statistical significant ($p < 0.05$)

Table 5 Summary of rate of local recurrence and complications

Author	Year	Local recurrence	Fusion rate	Sample size	Complications	
					Types	Rate
Shen, et al.	2022	1/13	-	1/13	Asymptomatic pseudomeningocele, Distal Junctional kyphosis, Chyle leak, Posterior construct revised, DVT/PE Pleural	0.35
Müther, et al.	2021	0/7	-	0/7	-	-
Neal, et al.	2021	3/28	-	3/28	11 death (39%)	0.39
Trungu, et al.	2021	0/51	-	0/51	Postoperative dysphagia	1 (5.9%)
Boriani, et al.	2020	2/6	-	2/6	-	-
Cofano, et al.	2020	2/36	-	2/36	1 CSF leakage (2.7%) 1 Wound Dehiscence (2.7%) 0 Breakage of screws, rods or plates	0.02
		5/42	-	5/42	1 CSF leakage (2.2%) 1 Neurological worsening (2.2%) 2 Wound Dehiscence (4.4%) 1 Infections (2.2%) 1 Screw Loosening (2.2%)	0.06
Sakaura, et al.	2019	-	103 (80.5%)	-	-	-
Pipola, et al.	2020	0/1	0/1	0/1	0	0
Tan, et al.	2013	0/28	-	0/28	3 Deep venous thrombosis 1 wound drainage 1 decrease in renal function	0.18
Anselmetti, et al.	2013	2/40	-	2/40	Death: 3 (after 3 m); 3 after 6 m) New vertebral fracture: 3 CSF Leakage: 7/43	Leakage: (16.3%)
Boriani, et al.	2018	6/34	-	6/34	Screw breakage (1) Loosening of sacral screw (2) after 9–12 months	0.03
Laux, et al.	2018	0/1	0/1	0/1	0	0
Ringel, et al.	2017	-	-	-		-
Tedesco, et al.	2017	7/17	-	7/17	-	-
Rajpal, et al.	2012	-	-	-	5 deep venous thrombosis 5 pneumonias 3 mental status changes, 1 postoperative ileus, urinary tract infection, sepsis, thrombocytopenia, respiratory failure, pneumothorax, and pulmonary edema	0.432
Burkett, et al.	2012	0/29	-	0/29	Retropharyngeal hematoma	0.03
Disch, et al.	2011	1/20	-	1/20	Major complications: 2 chylus fistula, 1 postoperative ileus, 1 pancreatitis, 1 Dural sac compressing hematoma 1 persistent neurologic deficit Minor complications: 3 healing disturbances, 1 CSF leakage, 2 temporary neurologic deficits, 1 hematoma	-
Jang, et al.	2002	-	-	-	-	-
Schulte, et al.	2000	0/5	-	0/5	0	0

Fusion Rate: the percentage of patients with successful spinal fusion at follow-up; rate: the percentage of patients reporting said complications

Safety of CFR-PEEK in metastatic spine tumor surgery

The consensus among the authors of the reported studies is that radiolucent implanted devices exhibit low implant failure rates and are reliable alternatives to traditional systems in the treatment of vertebral tumors. Specifically, Boriani and colleagues [47] described only 1 case of intraoperative screw breakage that occurred in 232 radiolucent screw placements in a short-term period. In the long-term postoperative setting (mean follow-up

Table 6 MINORS

Author		Clearly stated aim	Inclusion of consecutive patients	Prospective data collection	Endpoints appropriate to study aim	Unbiased assessment of study endpoint	Follow-up period appropriate to study aim	< 5% lost to follow-up	Prospective calculation of study size	Adequate control group	Contemporary groups	Baseline equivalence of groups	Adequate statistical analyses	Total score (…/16)
NON COMPARATIVE STUDIES														
Schulte	2000	2	2	1	2	0	2	2	0	-	-	-	-	11
Jang	2002	1	0	0	1	0	2	1	0	-	-	-	-	5
Disch	2011	1	2	0	2	0	2	2	0	-	-	-	-	9
Rajpal	2012	2	1	2	2	0	2	2	0	-	-	-	-	11
Burkett	2012	1	0	1	1	0	1	2	0	-	-	-	-	6
Anselmetti	2013	1	2	0	2	0	1	2	0	-	-	-	-	8
Tan	2013	1	2	0	2	0	1	2	0	-	-	-	-	8
Anselmetti	2013	1	2	0	2	0	1	2	0	-	-	-	-	8
Ringel	2017	1	1	0	2	0	2	2	0	-	-	-	-	8
Tedesco	2017	2	2	2	2	0	2	2	0	-	-	-	-	12
Boriani	2018	2	2	2	2	0	2	2	0	-	-	-	-	12
Laux	2018	1	0	1	1	0	1	2	0	-	-	-	-	6
Boriani	2020	2	2	2	2	0	2	2	0	-	-	-	-	12
Pipola	2020	2	0	1	1	0	2	2	0	-	-	-	-	8
Wagner	2021	1	1	0	2	0	2	2	0	-	-	-	-	8
Neal	2021	2	2	0	2	0	2	2	0	-	-	-	-	10
Trungu	2021	2	2	2	2	0	2	2	0	-	-	-	-	12
Shen	2022	2	1	0	2	0	1	2	0	-	-	-	-	8
COMPARATIVE STUDIES														Total score (…/24)
Sakaura	2019	1	1	2	2	0	2	2	0	2	2	1	2	17
Cofano	2020	2	2	0	2	0	2	2	0	2	1	2	2	17

of 13 months), only two patients displayed a loosening of the sacral screw.

In direct comparison with titanium implanted devices, CFR-PEEK demonstrates a non-inferior profile concerning intraoperative and postoperative complications, as well as functional recovery [35]. This has been reported in a study by Cofano et al. [35], in which thirty-six patients who received CFR-PEEK implanted devices for anterior spinal reconstruction were compared with 42 patients who had previously received titanium implanted devices. No screw breakage was observed in either of the groups. The latter study exhibits similar limitations to the previously cited one by Boriani, meaning it has a small sample size and heterogenous instrumentation, though also lacks a follow-up long enough to draw any conclusions on the oncological benefits of CFR-PEEK.

In another retrieved study, conducted by Anselmetti et al. [58], it was stated that CFR-PEEK implanted devices show promise in reducing the risk of PMMA extravasation as compared to conventional vertebral augmentation techniques. This due to the unique design of these novel composite implanted materials. However, it has to be stated that the studies in question did show some shortcomings, such as a small and heterogenous sample size and the use of different materials in the reconstruction of the anterior column, and also lacked a cost-benefit analysis regarding the production of the implanted devices. Nevertheless, the safety and effectiveness of this novel device warrant further exploration through prospective studies with larger patient cohorts to ensure its reliability in the context of metastatic spine tumors.

Advantages of CFR-PEEK in imaging and radiotherapy

The benefits of CFR-PEEK composite implanted devices in imaging definition and radiotherapy in the postoperative setting have been emphasized in most of the reviewed studies. PEEK's radiolucency and excellent imaging properties bring significant advantages in postoperative radiotherapy, allowing for precise administration of the maximum dose on the target lesion while minimizing radiotoxicity in surrounding tissues [24, 47–57, 69]. Boriani et al. [48] have studied the benefits of CFR-PEEK composite implanted devices in imaging definition and radiotherapy in the postoperative setting. These granted excellent imaging definition, with no scattering effects and minimal artifact production. The therapeutic approach to primary tumours often involves radiation therapy, a notably artifact-sensitive technique [24, 55]. Titanium produces higher HU variation between the screw and surrounding tissue, influencing dosimetry. Furthermore, during RT, titanium screws cause 60–80% dose reduction behind the screws, while CFR-PEEK is associated with a 10% reduction [15].

Another study, conducted by Laux et al. [61], showed different though favorable results, with fewer artifacts on both CT and MRI. Furthermore, CFR-PEEK showed minimal dose alteration, with an attenuation of approximately 5%.

However, findings by this and other cited studies should be validated by further studies analyzing the long-term stability of these implanted devices in a different population with longer-term follow up.

PMMA vertebral augmentation

Several authors used PMMA for vertebral augmentation with titanium and radiolucent screws. No differences were reported in term of complications or advantages, other than the potential reduction of PMMA extravasation when used in conjunction with CFR-PEEK [58]. Therefore, it may be assumed that PMMA augmentation could be used also with new radiolucent implanted devices [70, 71].

Limitations

The present review has six limitations. First, the study did not include randomized control trials or low-quality studies. Second, the meta-analysis of results could not be performed due to the heterogeneity of the collected data. Third, English-language restraint limited the number of eligible articles. Fourth, only one study reported the fusion rate, and few reported an influence on RT management. Fifth, the time and the type of recurrence was not reported. Sixth, different treatments and tumours were included, making it impossible to compare data. Further trials are needed to determine the applicability of each material in different contexts. These should employ homogenous instrumentation in all patients, grouping them based on different types of tumors, then comparing them with a control group. Cost-benefit analyses should also be performed in future studies, so as to properly understand the economic implications of employing new materials in this context.

Conclusions

The studies exhibited the potential benefits of utilizing radiolucent materials, such as CFR-PEEK, in the context of MSTS. These studies presented compelling evidence regarding the reduction of artifact production, making postoperative management more effective and enhancing the compatibility with adjuvant radiotherapy.

However, it is important to recognize certain limitations in the reviewed studies. Some studies had relatively small sample sizes, limiting the generalizability of their findings to a broader patient population. Additionally, long-term follow-up data were often lacking, making it challenging to evaluate the durability and longevity of the implanted devices, especially in the context of potential

implant failures over extended periods. Furthermore, the cost implications associated with using complex materials like CFR-PEEK were not comprehensively addressed in the studies, which could be a crucial consideration in real-world clinical settings.

Among the reviewed studies, CFR-PEEK emerged as the material demonstrating the best clinical performance. The advantages of CFR-PEEK, including its noninferior safety profile compared to titanium, minimized artifact production, and reduced dose perturbation effects during adjuvant radiotherapy, make it a promising candidate for replacing traditional titanium alloys in MSTS.

To advance the understanding of radiolucent implanted devices and improve future clinical studies, three recommendations are made. First, future research should prioritize large-scale, well-designed clinical trials with a homogenous patient sample affected by similar types of tumors, utilizing standardized instrumentation for spine reconstruction. Second, long-term follow-up should be integral to these trials to assess the durability and potential complications of the implanted devices. Third, cost-benefit analyses should be incorporated into future studies to evaluate the economic feasibility of implementing these complex materials in routine clinical practice. By addressing these considerations, future research can provide a more comprehensive understanding of the clinical performance and applicability of radiolucent implanted devices in the realm of spine tumor surgery.

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