CFR-PEEK

Vertebral body replacement (VBR) using CFR PEEK cages represents a legitimate surgical strategy that opens a variety of improvements-especially in patients in need of postoperative radiotherapy of the spine and MRI-based follow-up examinations [1].

Protocols including a combination of surgery and radiotherapy are more and more frequent in the treatment of bone tumors of the spine. In metastatic disease, a combination of surgery and radiotherapy is since a long time accepted, based on clinical evidence. In primary tumors, a combination of surgery and radiotherapy can be considered in all the cases in which a satisfactory oncological margin cannot be achieved: high-grade malignancies, recurrent tumors, huge tumors expanding in an extracompartimental area, and when tumor-free margin requires unacceptable functional sacrifices. However, metal implants are an obstacle to the collaboration between surgeons and radiation oncologists. Carbon-fiber-reinforced polyether-ether-ether-ketone (CFR-PEEK) composite implants could make them easier and more effective in the treatment as radiolucent and not interfere with ionizing radiation and accelerated particles.

The purpose of this article is to report the preliminary results from a cohort of patients treated with CFR-PEEK and to evaluate the safety and the non-inferiority of the device with respect to the commonly used titanium implants.

MATERIALS AND METHODS: This study concerns an ambispective cohort series of 34 tumor patients (14 metastases and 20 primaries, most of them recurrent) submitted to thoracic and lumbar spine fixation with CFR-PEEK composite implants. Oncologic surgery was palliative decompression and fixation in 9 cases, tumor excision in 21, and en bloc resection in 4. Data collected for this preliminary report were all intraoperative remarks, incidence of complications, changes in neurological status, local control, and survival. All the cases were followed 6-36 months (mean 13 months).

RESULTS: Only one intraoperative screw breakage occurred out of 232 implanted screws. Pain control and neurological improvement were the early clinical results. Two sacral screws loosening were found at 9 and 12 months in multilevel constructs performed on multirecurrent tumors. Six local recurrences were early found thanks to the implant radiolucency. Radiation oncologists' opinion was favourable as concerning better treatment planning on CT and lacking of scattering effect during the treatment.

CONCLUSIONS: No artifacts on imaging studies mean early local recurrence detection. For radiation oncologists, no artifacts on imaging studies mean easier planning and no scattering effect means more effective and safe radiotherapy, particularly when particles are used. Moreover, it seems that the clinical use of CFR-PEEK composite implants may be safe and at least comparable with the commonly used titanium implants in terms of intraoperative complications, stability at weight bearing and at functional recovery. Larger patient series and longer follow-up are required to confirm these data [2].

The aim of a study was to evaluate the dosimetric impact caused by recently introduced carbon fiber reinforced polyetheretherketone (CF/PEEK) stabilization devices, in comparison with conventional

titanium (Ti) implants, for post-operative particle therapy (PT).

As a first step, protons and carbon ions Spread-Out Bragg Peaks (SOBPs) were delivered to CF/PEEK and Ti screws. Transversal dose profiles were acquired with EBT3 films to evaluate beam perturbation. Effects on image quality and reconstruction artifacts were then investigated. CT scans of CF/PEEK and Ti implants were acquired according to our clinical protocol and Hounsfield Unit (HU) mean values were evaluated in three regions of interest. Implants and artifacts were then contoured in the sample CT scans, together with a target volume to simulate a spine tumor. Dose calculation accuracy was assessed by comparing optimized dose distributions with Monte Carlo simulations. In the end, the treatment plans of nine real patients (seven with CF/PEEK and two with Ti stabilization devices) were retrospectively analyzed to evaluate the dosimetric impact potentially occurring if improper management of the spine implant was carried out.

As expected, CF/PEEK screw caused a very slight beam perturbation in comparison with Ti ones, leading to a lower degree of dose degradation in case of contouring and/or set-up uncertainties. Furthermore, CF/PEEK devices did not determine appreciable HU artifacts on CT images thus improving image quality and, as a final result, dose calculation accuracy.

CF/PEEK spinal fixation devices resulted dosimetrically more suitable than commonly-used Ti implants for post-operative PT [3)].

Combination of surgery and radiotherapy in the treatment of primary spine tumour can be indicated in some cases where a satisfactory oncological margin cannot be achieved. The presence of metal hardware has always limited post-operative radiotherapy due to the scattering effects of ionizing radiation or particles. The use of a fixation system (including rods and screw) fully made in PEEK embedded Carbon fiber (CFR-PEEK) could make easier and more effective the post-operative radiotherapy as it is radiolucent and does not interfere with ionizing radiation and accelerated particles.

An ambispective study was performed on the first 22 consecutive primary tumor patients, who underwent spinal surgery including a composite CFR-PEEK fixation system. Oncologic surgery was palliative decompression and fixation in 3 cases; tumor excision in 15; en bloc resection in 4. The incidence of complications (intra- and postoperative), local control (LC) and local recurrence (LR), and changes in neurological status were considered.

Only one intraoperative screw breakage occurred and one case of loosening of sacral screws were found at 12 months in one patient. No rod breakage, neither any screw/rod disconnection was found. Post-operative RT has been performed in 19 patients. The overall number of progression of the tumour or LR was 7. The actuarial rate of LR or progression of the tumour, calculated according to the Kaplan-Meier method, was 17.6% at 12 months.

The CFR-PEEK fixation system is comparable to standard titanium system in term of intraoperative complications, stability at weight bearing and at functional recovery. Thanks to radiolucency CFR-PEEK stabilization devices are more suitable in patients eligible for RT: the absence of image artifacts together with significantly less dose perturbation improve the treatment accuracy. Moreover the radiolucency is useful in the follow-up of patients thus allowing early detection of LR [4)].

Bartels RH, Donk RD, Feuth T. Subsidence of stand-alone cervical carbon fiber cages. Neurosurgery.

2006 Mar;58(3):502-8; discussion 502-8. PubMed PMID: 16528190.

Carbon-fiber-reinforced polyetheretherketone (CFR-PEEK) has been successfully used in orthopedic implants. The aim of this systematic review is to investigate the properties, technical data, and safety of CFR-PEEK biomaterial and to evaluate its potential for new innovation in the design of articulating medical devices. A comprehensive search in PubMed and EMBASE was conducted to identify articles relevant to the outcomes of CFR-PEEK orthopedic implants. The search was also expanded by reviewing the reference sections of selected papers and references and benchmark reports provided by content experts. A total of 23 articles were included in this review. There is limited literature available assessing the performance of CFR-PEEK, specifically as an implant material for arthroplasty systems. Nevertheless, available studies strongly support CFR-PEEK as a promising and suitable material for orthopedic implants because of its biocompatibility, material characteristics, and mechanical durability. Future studies should continue to investigate CFR-PEEK's potential benefits [5)]

Case series

Müther et al. from the Münster University Hospital presented a technical note and according case series of seven patients with dumbbell tumors in the lumbar and thoracolumbar spine operated on between 2017 and 2020. CFR-PEEK pedicle screws and rods were inserted percutaneously. Afterwards, a dedicated self-standing retractor for posterolateral approaches was connected to the screws. Following a unilateral facetectomy the tumor was resected in a microsurgical fashion. Clinical data are reported with respect to the PROCESS guidelines.

Four patients presented with de-novo tumors. Three patients were treated for residual tumor mass after previous surgeries. Gross-total resection was achieved in all seven cases as demonstrated by early postoperative MRI. Histopathology demonstrated five WHO grade I schwannomas, one grade II hemangiopericytoma and one cavernous hemangioma. No postoperative complications were observed. CFR-PEEK hardware allowed unambiguous visualization of the resection cavity on follow-up imaging.

Resection of dumbbell tumors via a minimally invasive posterolateral approach and instrumentation with CFR-PEEK hardware allows maximal safe resection. Due to lack of major metal artifacts, carbon fiber hardware improves the interpretation of follow-up imaging as well as planning of radiation if required for tumor recurrence [6)].

1)
Schwendner M, Ille S, Kirschke JS, Bernhardt D, Combs SE, Meyer B, Krieg SM. Clinical evaluation of vertebral body replacement of carbon fiber-reinforced polyetheretherketone in patients with tumor manifestation of the thoracic and lumbar spine. Acta Neurochir (Wien). 2023 Feb 23. doi: 10.1007/s00701-023-05502-z. Epub ahead of print. PMID: 36820888.
2)
Boriani S, Tedesco G, Ming L, Ghermandi R, Amichetti M, Fossati P, Krengli M, Mavilla L, Gasbarrini A. Carbon-fiber-reinforced PEEK fixation system in the treatment of spine tumors: a preliminary report. Eur Spine J. 2018 Apr;27(4):874-881. doi: 10.1007/s00586-017-5258-5. Epub 2017 Aug 16. PubMed PMID: 28815357.
3)
Mastella E, Molinelli S, Magro G, Mirandola A, Russo S, Vai A, Mairani A, Choi K, Fiore MR, Fossati P, Cuzzocrea F, Gasbarrini A, Benazzo F, Boriani S, Valvo F, Orecchia R, Ciocca M. Dosimetric

characterization of carbon fiber stabilization devices for post-operative particle therapy. Phys Med. 2017 Dec;44:18-25. doi: 10.1016/j.ejmp.2017.11.008. Epub 2017 Nov 14. PubMed PMID: 29254587.
4)

Tedesco G, Gasbarrini A, Bandiera S, Ghermandi R, Boriani S. Composite PEEK/Carbon fiber implants can increase the effectiveness of radiotherapy in the management of spine tumors. J Spine Surg. 2017 Sep;3(3):323-329. doi: 10.21037/jss.2017.06.20. Erratum in: J Spine Surg. 2018 Mar;4(1):167. PubMed PMID: 29057339; PubMed Central PMCID: PMC5637210.
5)

Li CS, Vannabouathong C, Sprague S, Bhandari M. The Use of Carbon-Fiber-Reinforced (CFR) PEEK Material in Orthopedic Implants: A Systematic Review. Clin Med Insights Arthritis Musculoskelet Disord. 2015 Feb 23;8:33-45. doi: 10.4137/CMAMD.S20354. PMID: 25780341; PMCID: PMC4344123.
6)

Müther M, Lüthge S, Gerwing M, Stummer W, Schwake M. Management of spinal dumbbell tumors via a minimally-invasive posterolateral approach and carbon fiber reinforced PEEK instrumentation: technical note and surgical case series. World Neurosurg. 2021 Apr 26:S1878-8750(21)00609-4. doi: 10.1016/j.wneu.2021.04.068. Epub ahead of print. PMID: 33915306.