

## A comparative study of the role of carbon fibre reinforced polyetheretherketone and titanium intramedullary nails in patients with metastatic bone disease

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Carbon fibre reinforced polyetheretherketone (CFR-PEEK) implants have gained interest because of reported biomechanical advantages and radio-lucent properties. The aim of this study was to evaluate the role of CFR-PEEK nails in patients with metastatic bone disease (MBD). We performed a retrospective cohort study evaluating patients with MBD undergoing intramedullary (IM) nailing for prophylaxis or fixation of pathological fractures using CFR-PEEK or titanium implants. Patient survival, implant failure rates, ability to visualise disease progression on post-operative CT/MRI, and post-operative radiotherapy dose were reported. Fifty patients underwent 56 IM nails (26 CFR-PEEK and 30 titanium). Median survival was 8 months for the entire cohort, 6 months for patients with CFR-PEEK nails and 8 months for those with conventional nails ( $p=0.691$ ). No implant failures were recorded in either group. There was no correlation between implant type and post-operative radiotherapy dose given ( $\chi^2 = 0.139$ ,  $p=0.710$ ). Artefact on MRI was less evident with CFR-PEEK nails when hybrid imaging and metal artefact reduction techniques were used. The advantages of CFR-PEEK nails might not be realised in clinical practice for most patients with MBD requiring IM nailing except for in those likely to require prolonged disease surveillance.

**Keywords:** Metastatic bone disease, intra-medullary fixation, CFR-PEEK.

### INTRODUCTION

Metastatic bone disease (MBD) is a significant source of morbidity for patients, and appropriate management with medical and/or surgical treatment options requires a multidisciplinary approach<sup>1</sup>. Intramedullary (IM) nailing is an established form of operative management in long bones for stabilisation of lesions with impending fracture or fixation of pathological fractures with low failure rates<sup>2,3</sup>. This has conventionally been performed with radio-opaque metal nails (e.g. stainless steel or titanium) due to their strength, low cost and corrosion resistance<sup>2,4,5</sup>. However, disadvantages of this type of nail include mismatched modulus of elasticity, limited fatigue life, and less accurate visualisation of local structures on radiographic imaging due to their radio-opaque nature<sup>5</sup>.

Carbon fibre reinforced polyetheretherketone (CFR-PEEK) implants have gained interest in recent years as an alternative to conventional metal implants due to their biomechanical advantages and radio-lucent

properties<sup>6</sup>. Implants can be engineered to a specific strength and stiffness, achieving improved fatigue resistance and compliance compared to metal implants, with a modulus of elasticity closer to that of cortical bone<sup>5</sup>. A study by Ziran et al. found that CFR-PEEK nails used in tibial fractures had accelerated healing times compared to titanium nails; this was thought to be secondary to the biomechanical properties of the nail providing a more optimal healing environment<sup>7</sup>. Their non-inferiority to conventional metal nails was shown in a study by Takashima et al. who found a high union rate and no hardware failures in a group of 20 patients treated with CFR-PEEK nails for proximal femoral fractures<sup>8</sup>. CFR-PEEK implants are commonly used in spinal fusion surgery, as their radiolucent properties allows for improved assessment of fusion on post-operative imaging due to reduced artefact<sup>5,9,10</sup>.

The radiolucent nature of these implants has made their use in patients with MBD more appealing, with studies showing improved monitoring of disease with regards to local recurrence, progression and response

to treatment<sup>11-13</sup>. Moreover, there is evidence to suggest these implants have reduced perturbation effects on radiotherapy dose distribution<sup>14,15</sup>. However, these benefits must be considered in the context of their increased cost in a group of patients whose treatment can already be resource intensive. In 2020, the cost of CFR-PEEK nails was 92% greater than the titanium equivalent in our institution and the increased cost of these implants has previously been reported<sup>7,9,13</sup>. This consideration is important given the rising costs of health care provision driving current emphasis on value-based healthcare; a recent independent report of productivity and performance of the National Health Service hospitals in England highlighted potential annual savings of £5 billion through reducing unwarranted variations in cost of resources<sup>16</sup>. Studies of CFR-PEEK implants for patients with MBD have mostly been limited to case studies and case series with small sample sizes, and whether these theoretical benefits translate into clinical benefits remains unclear.

The aim of this study was to evaluate the role of CFR-PEEK IM nails versus conventional metal IM nails in patients with MBD disease, including multiple myeloma, with regard to patient survival, post-operative radiotherapy treatment, implant failure rates and ability to monitor disease progression on post-operative CT/MRI. The analysis in this study was a retrospective review of already available, anonymised data; therefore, Research Ethics Committee Approval was deemed not to be necessary for our Institution.

## MATERIALS AND METHODS

### *Study Design*

We performed a retrospective cohort study of all patients referred to our trauma and orthopaedic department via the MBD referral pathway between January 2016 and November 2020 at a university hospital with a large oncology service. Patients referred via this pathway include those with painful lesions, impending fractures, and/or pathological fractures. Using our database of MBD referrals, for which we prospectively collect data for auditing purposes, we included patients with metastatic bone disease who underwent IM nailing for prophylactic fixation of lesions or treatment of pathological fractures. Exclusion criteria included patients below the age of 18, patients managed non-operatively, and patients managed surgically with implants other than IM nails.

The included patients were further divided into those receiving CFR-PEEK nails (CarboFix Orthopedics Ltd., Herzeliya, Israel) and those receiving conventional titanium nails (Stryker, Michigan, U.S.A; Acumed

LLC, Oregon, U.S.A; DePuy Synthes, Massachusetts, U.S.A) for comparative analysis. The decision of using CFR-PEEK nails rather than metal nails was based on surgeon preference and availability of CFR-PEEK nail at time of surgery. There were no predetermined guidelines involved in the decision-making process.

### *Data collection*

The primary outcome measure was patient survival in months following IM nailing. Secondary outcome measures included implant failure rate, the ability to monitor disease progression on post-operative imaging and the total post-operative radiotherapy dose administered in gray (Gy) where applicable.

We also evaluated patient demographic data including age at surgery, gender, number of co-existing comorbidities as well as diagnostic data including the type of primary malignancy and affected bone.

### *Data analysis*

Statistical analysis was performed using Statistical Package for the Social Sciences (SPSS) 23 (IBM Corp., Armonk, NY) and Microsoft Excel for Windows 2010 (Microsoft, Redmond, WA). Statistical significance was set at  $p < 0.05$ .

Differences in frequency of post-operative radiotherapy treatment and doses given between both groups were analysed with Chi-square test. Survival probability was calculated using a Kaplan-Meier analysis and a log rank test was used to test for differences in survival between the two groups. Post-operative CT/MRI images of CFR-PEEK and metal nails were compared with regards to amount of artefact produced by analysing the impact on the radiologists' ability to comment on local disease progression on their written reports. This was an analysis of already available imaging arranged for monitoring of underlying disease progression, response to oncological treatment, and/or investigation of new symptoms or signs. Implant failures were detected by analysis of available post-operative imaging (plain radiograph, CT and/or MRI) and clinical notes.

## RESULTS

We identified 239 referrals made via our MBD referral pathway during the study period. Of these, 50 patients (31 females and 19 males) with a mean age of 63 years (range 33 – 92 years) underwent IM-nailing for pathological fracture and/or prophylaxis (Table I). The most common primary diagnoses included multiple myeloma in 21 patients, lung carcinoma in 10 patients and breast carcinoma in 9 patients, and the femur was

the most commonly involved long bone, requiring IM fixation in 43 patients. Six patients underwent 2 procedures, 1 of whom underwent a CFR-PEEK nail with subsequent titanium nail on the contralateral side (Table II).

**Table I.** — Demographic data of patients included in the study.

|  |           |
|--|-----------|
| Patients (N)                                   | 50        |
| Male N   | 19        |
| Female N                                       | 31        |
| Age (Mean ± SD)                                | 63 ± 13.5 |
| Primary Malignancy (N)                         |           |
| Multiple Myeloma                               | 21        |
| Lung Cancer                                    | 10        |
| Breast Cancer                                  | 9         |
| Prostate Cancer                                | 2         |
| Other  | 8         |
| Patients with three or more co-morbidities (N) | 21        |
| Hypertension                                   | 18        |
| Type 2 Diabetes Mellitus                       | 7         |
| Hypercholesterolaemia                          | 4         |
| Total IM Nails (N)                             | 56        |
| CFR-PEEK Nails                                 | 26        |
| Prophylactic                                   | 20        |
| Pathological fracture                          | 6         |
| Titanium Nails                                 | 30        |
| Prophylactic                                   | 18        |
| Pathological fracture                          | 12        |
| Affected bone (N)                              |           |
| Femur  | 43        |
| Humerus  | 11        |
| Radius   | 1         |
| Tibia  | 1         |

**Table II.** — Demographic data of patients who underwent more than one procedure.

|           | Age at surgery (years) | Sex    | Indication            | Affected bone | Nail type |
|-----------|------------------------|--------|-----------------------|---------------|-----------|
| Patient A | 72                     | Female | Pathological fracture | Left Humerus  | CFR-PEEK  |
|           | 74                     | Female | Prophylaxis           | Right Humerus | Titanium  |
| Patient B | 57                     | Female | Prophylaxis           | Humerus       | CFR-PEEK  |
|           | 57                     | Female | Prophylaxis           | Femur         | CFR-PEEK  |
| Patient C | 63                     | Female | Prophylaxis           | Right Femur   | CFR-PEEK  |
|           | 63                     | Female | Prophylaxis           | Left Femur    | CFR-PEEK  |
| Patient D | 67                     | Male   | Pathological fracture | Right Femur   | CFR-PEEK  |
|           | 67                     | Male   | Prophylaxis           | Left Femur    | CFR-PEEK  |
| Patient E | 66                     | Male   | Prophylaxis           | Humerus       | Titanium  |
|           | 66                     | Male   | Prophylaxis           | Femur         | Titanium  |
| Patient F | 48                     | Female | Prophylaxis           | Right Femur   | Titanium  |
|           | 48                     | Female | Prophylaxis           | Left Femur    | Titanium  |

### Survival Rates

One patient (Patient A, Table II) was excluded from survival analysis due to having both CFR-PEEK and metal implants. For other patients with more than 1 procedure, length of survival was based on the date of the first procedure.

By the end of the study period, 31 patients were deceased, of which 12 had been treated with CFR-PEEK nails and 19 had been treated with metal nails. Estimated median survival was 8 months (range 15 days– 60 months) in the whole cohort, 6 months (range 1 – 33 months) in patients receiving CFR-PEEK Nails, and 8 months (range 15 days– 60 months) in patients receiving metal nails. Log-rank test of equality showed no statistically significant difference in survival distributions between both groups ( $p = 0.691$ ). Kaplan-Meier plots of survival in patients treated with either type of nail, and for the entire cohort, can be found in Figures 1 and 2.

### Implant Failures

There were no documented implant failures or cases requiring revision surgery in either group. Two cases in the CFR-PEEK group sustained peri-prosthetic fractures post-operatively (Figure 3 and Figure 4). Both of these were fractures through the pathological lesion and detected incidentally on follow up imaging for disease surveillance in patients who underwent prophylactic nailing for proximal femoral lesions. The periprosthetic fractures for patient X and Y were noted at 3 weeks post operatively and 4 months post operatively, respectively. On retrospective questioning, patient Y reported onset of thigh pain and swelling following a fall a week prior to imaging. Both patients required no further intervention or imaging.

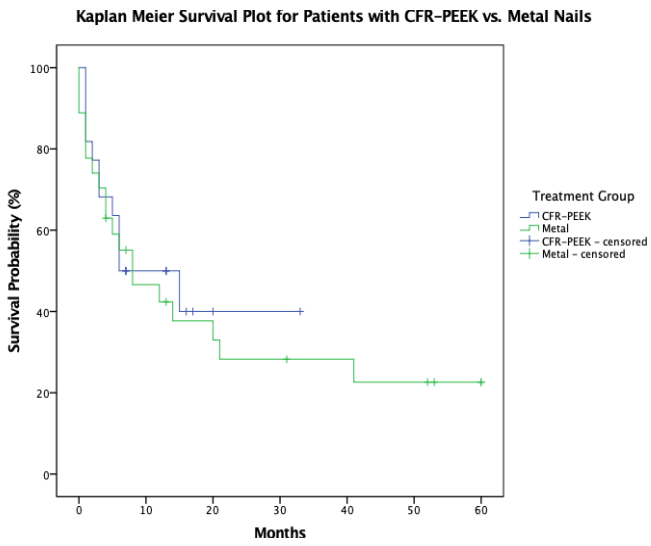


Fig. 1 — Kaplan Meier survival plot for patients treated with either type of nail.

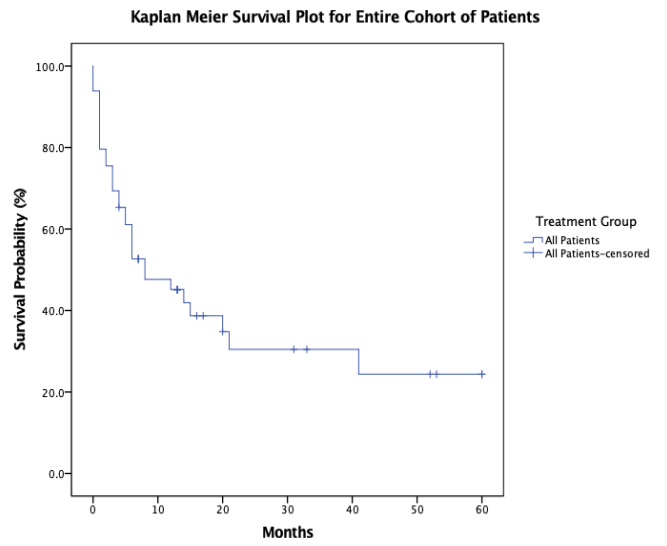


Fig. 2 — Kaplan Meier survival plot for entire cohort of patients.

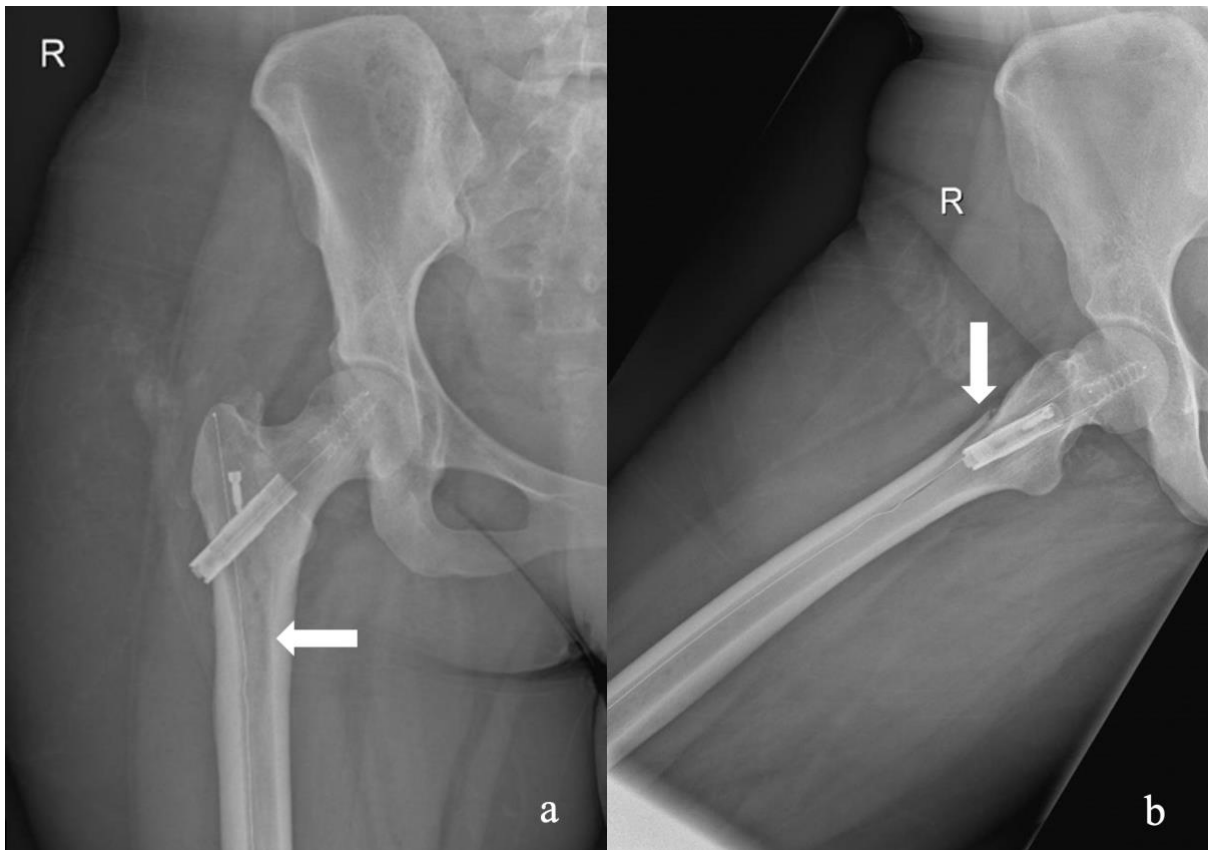


Fig. 3 — AP (a) and lateral (b) right femoral radiographs of Patient X with pathological fracture subsequent to prophylactic femoral CFR-PEEK IM nail.

*Post-operative Radiotherapy*

Results related to post-operative radiotherapy was based on number of IM nails (56) rather than number of patients. A total of 32 cases (26 prophylactic, 6 treatment) underwent post-operative radiotherapy; 21 of these received a 20 Gy dose in 5 fractions and 11 received

a one off 8 Gy dose. Both of these doses were palliative but those that were deemed medically fit enough to attend multiple sessions received the 20 Gy split dose (over 5 fractions) to reduce the exposure per radiotherapy session.

In the CFR-PEEK group, 16 cases (13 prophylactic, 3 treatment) underwent post-operative radiotherapy;





Fig. 4 — AP (a) and lateral (b) right femoral radiographs for Patient Y with a pathological fracture subsequent to prophylactic femoral CFR-PEEK IM nail.

11 of these received a 20 Gy dose in 5 fractions and 5 received a one off 8 Gy dose.

In the metal IM nail group, 16 cases (13 prophylactic, 3 treatment) received postoperative radiotherapy; 10 of these received a 20 Gy dose split over 5 sessions and 6 received a one off 8 Gy dose.

There was no statistically significant difference between both groups with regards to whether patients received radiotherapy post-operatively ( $\chi^2 = 0.383$   $p = 0.536$ ) or with regards to doses given ( $\chi^2 = 0.139$   $p = 0.710$ ) (Figure 5).

#### Ability to Visualise Disease Progression

Post-operative image analysis was based on number of IM nails (56) rather than number of patients. Thirty-two cases underwent post-operative imaging with CT or MRI.

Twenty cases underwent Full Body CT PET or Full Body MR PET scanning to evaluate disease progression following the insertion of an IM nail. Nine of these cases had titanium IM nails and 11 had CFR-PEEK IM nails. All 20 had radiologist reports commenting on disease progression without mention of artefact

obscuring anatomical detail.

Four cases had MRI imaging of their affected limbs, with 1 case having a metal IM nail and 3 cases having CFR-PEEK IM nails. The 1 case with a titanium IM and 1 case of the CFR-PEEK IM nails had artefact obscuring anatomical detail preventing evaluation of disease progression.

Twelve cases had CT imaging of their affected limbs, with 7 cases having a titanium IM nail and 5 cases having CFR-PEEK IM nails. All twelve cases had radiologist reports commenting on disease progression without mention of artefact obscuring anatomical detail.

Examples of the differences in artefact between the two types of nails on CT/MRI imaging are provided in Figure 6.

## DISCUSSION

To our knowledge, this is the first study to compare the role of CFR-PEEK nails with metal nails in patients with MBD with regards to patient survival, implant-related complications, post-operative radiotherapy

## Percentage of Cases Receiving Radiotherapy Post-operative IM Nail

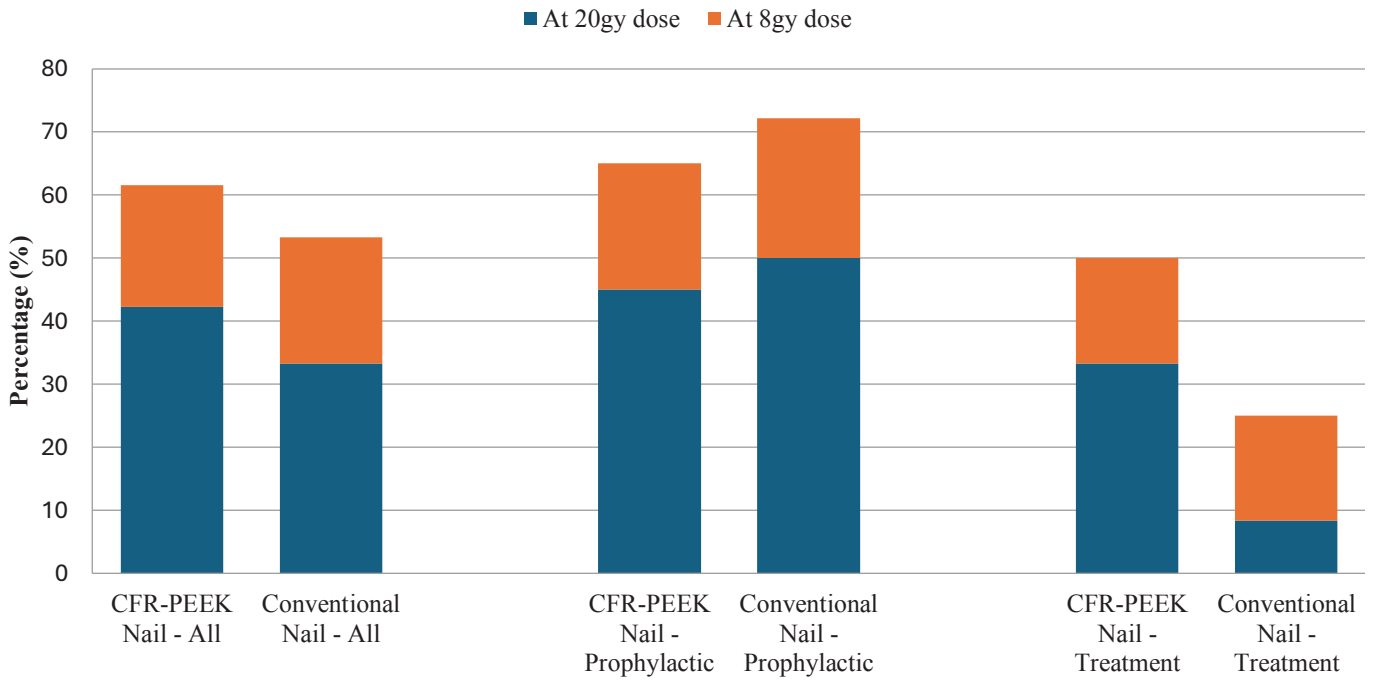


Fig. 5 — Chart showing percentage of cases receiving post-operative radiotherapy according to nail type.

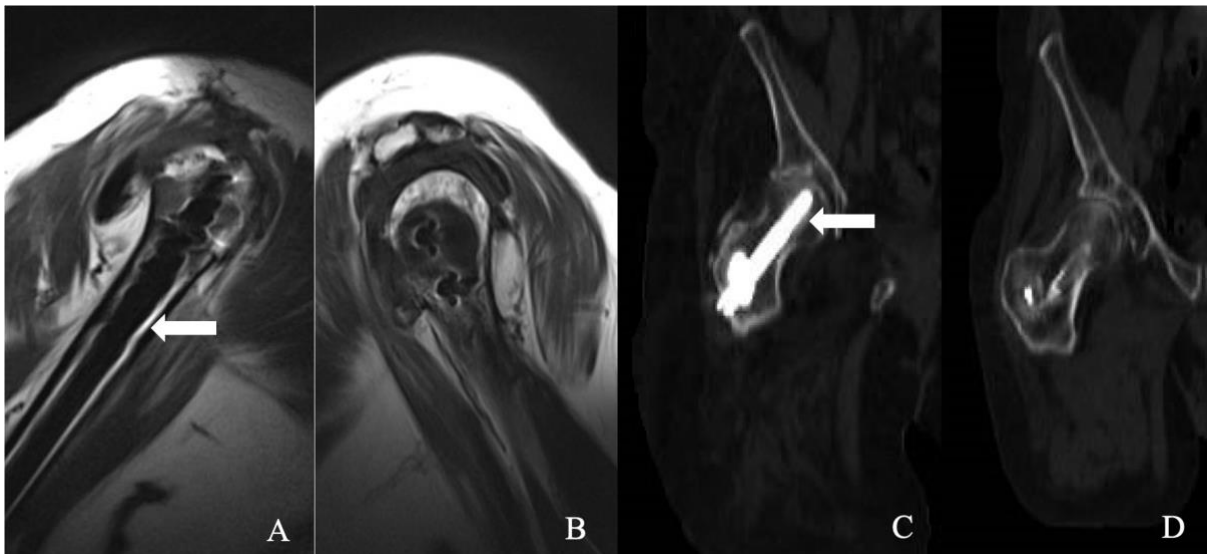


Fig. 6 — Follow-up MRI (T1 Sagittal view) of right humerus with a titanium IM nail in-situ, showing presence of artefact. B) Follow-up MRI (T1 Sagittal view) of left humerus of the same patient with a CFR-PEEK IM nail in-situ, showing the lack of artefact. C) Follow-up CT of right pelvis of a patient with a metal femoral IM nail in-situ, showing presence of artefact. D) Follow-up CT of right pelvis of a patient with a CFR-PEEK femoral IM nail in-situ, showing lack of artefact.

treatment, and ability to monitor disease progression. Our results show that approximately 2 in 5 patients undergoing IM nailing for pathological fracture or prophylaxis survive beyond 18 months, the dose of prophylactic radiotherapy is not altered because of the type of nail in situ, and treatment failures do not seem

to occur with either type of nail. These findings suggest that the majority of patients with MBD requiring IM nailing might not realise the proposed benefits of CFR-PEEK nails, such as an improved endurance limit, and improved targeting and dosing of radiotherapy. The benefit with regards to disease surveillance on post-

operative MRI-based imaging of CFR-PEEK nails when compared to conventional titanium nails appears to be less pronounced than expected when utilising hybrid imaging modalities such as PET-CT or PET-MRI.

The prognosis for survival of patients requiring surgery for MBD is dependent on several factors, such as primary cancer type, presence of multiple bone metastases and visceral metastases<sup>17</sup>. Survival following surgery for MBD is reportedly 79.1% - 80.9% at 12 months with the overall survival rate dropping to 62% - 75% from 3 to five years and as low as 48% at ten years in those with renal cell carcinoma<sup>17,18</sup>. Surgical intervention for patients with MBD is largely palliative, and the goal is to maintain the patient's level of function, ambulation and quality of life<sup>2</sup>. Biomechanical studies provide compelling evidence of improved fatigue resistance of CFR-PEEK IM nails, which may be beneficial for both pathological fractures and prophylaxis<sup>5,19</sup>. However, overall patient survival rates beyond 18 months in our cohort are low, and the goal of ambulation can be achieved with either type of nail. Those with more favourable prognosis may demonstrate more benefit from the biomechanical advantages of the CFR-PEEK nails. Using prognostic indicators and prognostic scores preoperatively can help in our decision-making process for which patients may seek biomechanical benefits with CFR-PEEK nails, although long-term follow up studies will be needed to demonstrate this<sup>20,21</sup>.

We observed 2 patients with CFR-PEEK nails with fractures through the pathological lesion that were detected on post-operative imaging for disease surveillance, not evident on immediate post-operative imaging. This may be explained by the similar modulus of elasticity between the CFR-PEEK nail and native femur<sup>5</sup>, and demonstrates that the femur is still loaded despite the nail in situ. This is a property that should be evaluated with further studies, as sharing load in this manner may favour callous formation and bone healing, and reduces the risk of proximal cut-out of the lag screw, provided the implant has sufficient fatigue resistance as suggested by biomechanical studies<sup>18</sup>.

Post-operative radiotherapy is utilised in patients with MBD to improve local disease control, pain and fracture risk<sup>2</sup>. Nevelsky et al. investigated the perturbation effects of vertebral pedicle screws and demonstrated that CFR-PEEK screws caused less than 5% perturbation of radiotherapy dose compared to more than 30% in titanium screws<sup>14</sup>. In cases where surgical intervention may be accompanied by radiotherapy that is intended to be curative, this

difference in perturbation may make a meaningful difference in efficacy and permit dose reduction. As demonstrated in our cohort, patients with MBD receive palliative doses of radiotherapy, which tend to be lower and aimed at symptom control rather than disease eradication as in cases intended to be curative. The doses are, therefore, not adjusted for the type of implant in this group, although it could be argued that the palliative radiotherapy administered is more effective if less perturbation is caused by the implant. Whether this has a meaningful clinical benefit (in controlling pain, for example) is not known. Studies evaluating clinical efficacy of radiotherapy in CFR-PEEK versus conventional nails in terms of symptom control are needed.

CFR-PEEK nails have been reported to produce less artifact on CT/MRI imaging<sup>22</sup>. A study by Zimel et al studied the post-operative CT and MRI imaging of a group of 8 adult oncology patients who received prophylactic femoral or tibial IM CFR-PEEK nails and compared them to a control group of 7 patients with prophylactic titanium femoral nails. The authors developed a 5-point scoring system evaluating the adjacent anatomic areas, which the radiologist used to grade imaging artifact and demonstrated that visualisation of cortex, corticomedullary junction, and the bone-muscle interface was significantly better in the CFR-PEEK group<sup>11</sup>. This effect was evident on post-operative MRI and CT imaging in our cohort of patients (Figure 6). Improved ability to evaluate local disease with cross sectional imaging plays a role in patients with MBD following resection and fixation to monitor disease progression<sup>23</sup>. However, artefact is not completely eliminated by using CFR-PEEK nails and was demonstrated in one patient undergoing post-operative MRI where the radiologist reported on sufficient artefact around the nail to obscure anatomical detail. The use of hybrid imaging modalities such as PET-CT and PET-MRI appeared to improve the radiologists' ability to evaluate disease progression, especially when metal artefact reduction techniques are utilised<sup>24</sup>. For patients who have a good prognosis and are expected to have prolonged disease surveillance of the affected limb, the CFR PEEK nails may have the advantage of less artefact on cross sectional imaging compared to those that have metal nails and this could justify the increased cost of CFR-PEEK nails.

Although the benefits of CFR-PEEK nails were unlikely to be realised in most patients in our study, the potential benefits of CFR-PEEK implants in other patient populations have also been investigated. A

systematic review by Theivendran et. al. found low certainty evidence to suggest a small improvement to functional recovery and time to union with CFR-PEEK implants in trauma surgery. However, they concluded that high powered randomised control trials were required before clinically relevant recommendations on their use could be made<sup>25</sup>. Another review of the use of CFR-PEEK implants in spine tumour surgery found limited but promising evidence to suggest biomechanical equivalence to titanium implants but the authors concluded that there was insufficient evidence to suggest reduced imaging artefact translated to improvements in disease control, mortality or patient reported outcomes<sup>26</sup>. Both studies highlight the need for further high powered, prospective comparative studies to investigate the impact of CFR-PEEK implants on patient outcomes.

There are limitations to our study. Firstly, CFR-PEEK nails have been used at our institution since 2016 and their follow up is, therefore, of shorter duration than patients who have undergone conventional titanium nailing. While we have compared these two groups, it is essential to highlight that the primary and secondary outcome measures for the entire cohort rather than the subgroup comparison were the focus of this manuscript in determining the recommendations. Secondly, we had no quantitative measure of the amount of artefact produced by the intramedullary nails on post-operative CT and MRI-based imaging, and the ability to evaluate disease progression or treatment response was based on the subjective evaluation of the radiologist. However, to our knowledge, no quantitative measure of artefact in this context exists yet. Furthermore, the radiologists reporting on the imaging for this cohort have specialist training and experience in musculoskeletal oncology, and their inability to evaluate disease progression demonstrates this impact in clinical practice. Finally, we were not able to evaluate the efficacy of the delivered radiotherapy dose or determine if a clinical difference in symptom control exists in accordance with the difference in perturbation between CFR-PEEK and titanium nails.

The majority of patients with MBD requiring IM nailing do not survive beyond 18 months and post-operative palliative radiotherapy is not dose-adjusted for the type of implant. Therefore, the compelling biomechanical advantages of CFR-PEEK nails are unlikely to be realised in clinical practice by most patients with MBD, with conventional nails providing a more cost-effective alternative. While less artefact is evident with CFR-PEEK nails, both nail types

can produce artefact on MRI imaging, which appear to be less concerning when using hybrid imaging modalities such as PET-MRI and with metal artefact reduction techniques. Further studies are needed to evaluate whether there is a difference in clinical efficacy of palliative radiotherapy in accordance with the difference in perturbation seen between CFR-PEEK and titanium nails. At present, patients requiring prolonged monitoring of disease and treatment response may benefit from the use of CFR-PEEK nails when considering their additional cost.

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