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ONCOLOGY

# Comparison of carbon fibre and titanium intramedullary nails in orthopaedic oncology

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## Aims

Due to their radiolucency and favourable mechanical properties, carbon fibre nails may be a preferable alternative to titanium nails for oncology patients. We aim to compare the surgical characteristics and short-term results of patients who underwent intramedullary fixation with either a titanium or carbon fibre nail for pathological long-bone fracture.

## Methods

This single tertiary-institutional, retrospectively matched case-control study included 72 patients who underwent prophylactic or therapeutic fixation for pathological fracture of the humerus, femur, or tibia with either a titanium (control group, n = 36) or carbon fibre (case group, n = 36) intramedullary nail between 2016 to 2020. Patients were excluded if intramedullary fixation was combined with any other surgical procedure/fixation method. Outcomes included operating time, blood loss, fluoroscopic time, and complications. Fisher's exact test and Mann-Whitney U test were used for categorical and continuous outcomes, respectively.

## Results

Patients receiving carbon nails as compared to those receiving titanium nails had higher blood loss (median 150 ml (interquartile range (IQR) 100 to 250) vs 100 ml (IQR 50 to 150); p = 0.042) and longer fluoroscopic time (median 150 seconds (IQR 114 to 182) vs 94 seconds (IQR 58 to 124); p = 0.001). Implant complications occurred in seven patients (19%) in the titanium group versus one patient (3%) in the carbon fibre group (p = 0.055). There were no notable differences between groups with regard to operating time, surgical wound infection, or survival.

## Conclusion

This pilot study demonstrates a non-inferior surgical and short-term clinical profile supporting further consideration of carbon fibre nails for pathological fracture fixation in orthopaedic oncology patients. Given enhanced accommodation of imaging methods important for oncological surveillance and radiation therapy planning, as well as high tolerances to fatigue stress, carbon fibre implants possess important oncological advantages over titanium implants that merit further prospective investigation.

Level of evidence: III, Retrospective study

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**Keywords:** Carbon fibre, Titanium nails, Orthopaedic oncology, Pathological fracture

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## Introduction

Despite the contribution of carbon fibre to dramatic paradigm shifts in other commercial and scientific industries,[1] carbon fibre has only relatively recently been incorporated into the medical field and into orthopaedic implants. Carbon fibre polyether ether ketone (CF-PEEK) is perhaps the most well-known application of carbon fibre presently in the field of orthopaedics. These implants are radiolucent, which offers immense imaging advantages over titanium implants as there is significantly decreased scatter on CT or susceptibility artifact on MRI. This is

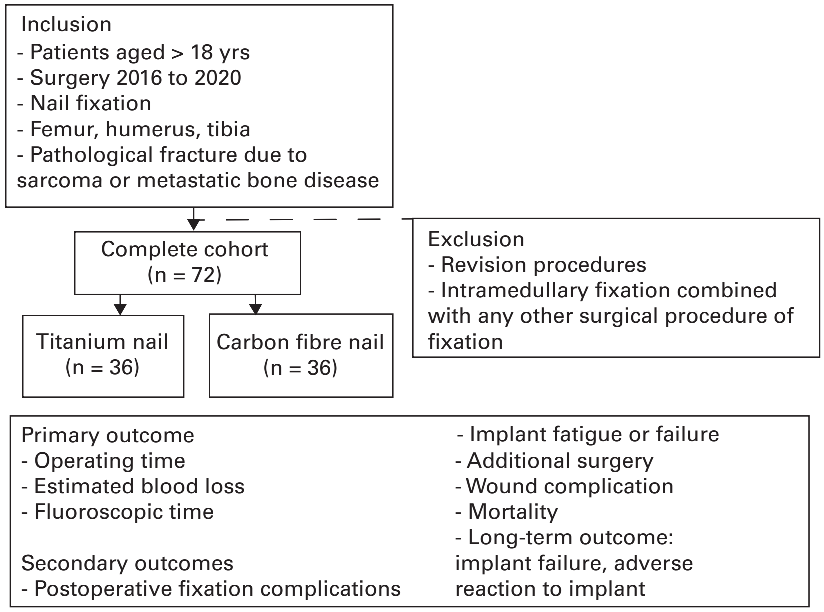


**Fig. 1**

Flow diagram illustrating patient selection and outcomes.

especially relevant for orthopaedic oncology, as radiolucent implants would allow for improved visualization of bone healing, postoperative surveillance for local disease recurrence or progression, and improved capability for radiation planning.[2,3]

The same performance characteristics apply when used for the treatment of primary sarcomas of bone or the soft tissues. In the former, these implants may be useful for allograft reconstruction, allowing for monitoring of allograft incorporation and local surveillance. For the latter, they may be helpful for prophylactic protection of bone that has been or will be irradiated as part of the treatment of a soft-tissue sarcoma, while also allowing improved ability for local surveillance. At present, there is a paucity of literature describing the use of carbon fibre-based implants for pathological fracture fixation.[4-6]

Therefore, in this study, we investigated the surgical characteristics and short-term results of a cohort of sarcoma patients and metastatic bone disease patients with primary tumours of different origins at our institution, who underwent either prophylactic or therapeutic fixation with a carbon fibre implant for either impending or completed pathological fracture. We hypothesized that surgical results and short-term clinical profiles would be similar between carbon fibre and titanium implant groups.

## Methods

**Study design and setting.** Our institutional review board approved a waiver of informed consent for this retrospective cohort study at a single tertiary-care institution in Northeast America. We adhered to the Strengthening Reporting of Observational Studies in Epidemiology (STROBE)[7] guidelines.

**Study subjects.** Patients included were aged 18 years or older, and underwent either prophylactic or therapeutic intramedullary nail fixation for pathological fracture (due to sarcoma or metastatic bone disease) of the humerus, femur, or tibia between 2016 and 2020 (Figure 1). Patients underwent either titanium intramedullary nailing (control group) or carbon fibre intramedullary nailing (case group). Patients in the carbon fibre and titanium nailing groups were matched for age, sex, malignancy (based on histological diagnosis), and implant location. Patients were excluded if intramedullary fixation was combined with any other surgical procedure or fixation. Only the index surgery was included if a patient received multiple surgeries meeting the selection criteria. Choice of nail was decided by discussion and informed consent by the patient and surgeon in all cases. During the study period, postoperative care was tailored to disease severity.

**Outcome measures and explanatory variables.** The primary outcomes were operating time (minutes), estimated blood loss (millilitres), and fluoroscopic time (seconds). The secondary outcomes were postoperative fixation complications, implant fatigue or failure, any additional surgery to the surgery site, surgical wound infection, and mortality.

Explanatory variables included demographic, radiological, and surgical data. The following variables were obtained from the electronic medical records: age, sex, BMI, preoperative white blood cell count, any Charlson comorbidity in addition to cancer,[8] surgeon (both surgeons were senior, fellowship-trained orthopaedic oncology surgeons (KAR, SLC)), primary tumour type

**Table I.** Characteristics of patients treated with titanium (n = 36) and carbon fibre nails (n = 36) for impending or completed pathological fractures.

| Variables | Titanium nail (n = 36) | Carbon fibre nail (n = 36) | p-value |
|---|---|---|---|
| Median age, yrs (IQR) | 67 (62 to 72) | 69 (63 to 75) | 0.332* |
| Median BMI, kg/m$^2$ (IQR) | 27 (23 to 30) | 24 (22 to 26) | 0.046* |
| Median preoperative white blood cell count (IQR) | 7.9 (5.7 to 11.6) | 7.3 (4.7 to 9.6) | 0.199* |
| Male, % (n) | 50 (18) | 39 (14) | 0.477† |
| Other modified Charlson comorbidity,‡ % (n) | 25 (9) | 33 (12) | 0.605† |
| **Primary tumour growth,§ % (n)** | | | 0.098† |
| Slow | 44 (16) | 28 (10) | |
| Moderate | 28 (10) | 28 (10) | |
| Rapid | 28 (10) | 44 (16) | |
| **Pathological fracture, % (n)** | | | 0.227† |
| Impending | 53 (19) | 69 (25) | |
| Completed | 47 (17) | 31 (11) | |
| **Tumour location, % (n)** | | | 0.704† |
| Femur | 61 (22) | 67 (24) | |
| Humerus | 36 (13) | 28 (10) | |
| Tibia | 3 (1) | 6 (2) | |
| **Limb, % (n)** | | | 0.614† |
| Lower limb | 64 (23) | 72 (26) | |
| Upper limb | 36 (13) | 28 (10) | |
| Preoperative radiation, % (n) | 19 (7) | 14 (5) | 0.753† |
| Postoperative radiation, % (n) | 31 (11) | 50 (18) | 0.149† |
| Median follow-up time, mths¶ (IQR) | 14 (2.3 to 38) | 9.5 (2.4 to 18.8) | 0.055* |

Estimated blood was available in 32 patients (89%) in the titanium group and 34 patients (94%) in the carbon fibre group. No other missing values were recorded.
*Mann-Whitney U test.
†Fisher's exact test.
‡These values were based on any additional comorbidity on top of the metastatic disease score according to the modified Charlson Comorbidity Index.
§Based on histology groupings; slow growth includes hormone-dependent breast cancer, hormone-dependent prostate cancer, malignant lymphoma, malignant myeloma, and thyroid cancer; moderate growth includes non-small cell lung cancer with molecularly targeted therapy, hormone-independent breast cancer, hormone-independent prostate cancer, renal cell carcinoma, sarcoma, other gynaecological cancer, and others; and rapid growth includes other lung cancer, colon, and rectal cancer, gastric cancer, hepatocellular carcinoma, pancreatic cancer, head and neck cancer, other urological cancer, esophageal cancer, malignant melanoma, gallbladder cancer, cervical cancer, and unknown origin.
¶One patient in the carbon fibre nail group was lost to follow-up after three days of discharge due to return to hometown that was out of the country; no special circumstances were noted during surgery or at discharge. The other 71 patients had at least one year of follow-up.
IQR, interquartile range.

categorized as slow, moderate, or rapid growth as classified by Katagiri et al,[9] pathological fracture, tumour location, preoperative radiotherapy to surgery site, and postoperative radiotherapy to surgery site. All explanatory variables were extracted while blinded for the outcomes. Neither surgeon has any conflict of interests regarding the type of nail.

**Statistical analysis.** Data did not pass Kolmogorov-Smirnov testing and visual histogram inspection for normality; as such, medians and interquartile ranges (IQRs) of the median are reported herein, and non-parametric statistical testing was used for comparison of continuous data with the Mann-Whitney U test and Fisher's exact test for categorical data. Estimated blood loss was available in 32 patients (89%) in the titanium group and 34 patients (94%) in the carbon fibre group. No other missing values were recorded. One patient in the carbon fibre nail group was lost to follow-up after three days of discharge due to return to his/her hometown that was out of the country; no special circumstances were noted during surgery or at discharge. The other 71 patients had at least one year follow-up. Statistical significance was defined as $p < 0.05$. All statistical analyses were performed using Stata v. 15.0 (StataCorp, USA).

## Results

**Study population.** In total, 72 patients were included with 36 patients in the carbon fibre nail group and 36 in the titanium nail group. The median age was 68 years (IQR 63 to 74); 64% of patients (46/72) underwent femoral fixation. Primary tumour growth groups included: slow growth in 36% (26/72), moderate growth in 28% (20/72), and rapid growth in 36% (26/72). Patients with a carbon fibre nail had a lower median BMI (24 kg/m$^2$ (IQR 22 to 26) vs 27 (IQR 23 to 30)). No other baseline differences were noted between both groups. Median follow-up was 14 months (IQR 2.3 to 38) for titanium group and 9.5 months (IQR 2.4 to 18.8) for carbon fibre group (Table I).

**Table II.** Outcomes of patients treated with titanium (n = 36) and carbon fibre nails (n = 36) for impending or completed pathological fractures.

| Outcomes | Titanium nail (n = 36) | Carbon fibre nail (n = 36) | p-value |
|---|---|---|---|
| Median operating time, mins (IQR) | 90 (65 to 120) | 80 (68 to 120) | 0.686* |
| Median estimated blood loss, ml† (IQR) | 100 (50 to 150) | 150 (100 to 250) | 0.042* |
| Median fluoroscopic time, seconds (IQR) | 94 (58 to 124) | 150 (114 to 182) | 0.001* |
| **Implant, % (n)** | | | |
| Rejection | 0 (0) | 0 (0) | N/A |
| Fatigue | 0 (0) | 0 (0) | N/A |
| Switch, % (n) | 11 (4) | 0 (0) | 0.115‡ |
| **Complication with implant, % (n)** | | | 0.055‡ |
| None | 81 (29) | 97 (35) | |
| Nonunion | 6 (2) | 3 (1) | |
| Periprosthetic | 11 (4) | 0 (0) | |
| Chronic pain | 3 (1) | 0 (0) | |
| Surgical wound infection, % (n) | 3 (1) | 8 (3) | 0.614‡ |
| **Mortality, % (n)** | | | |
| 90 days | 28 (10) | 26 (9) | 0.999‡ |
| One year | 44 (16) | 51 (18) | 0.638‡ |
| Overall | 69 (25) | 67 (24) | 0.999‡ |

*Mann-Whitney U test.
†Estimated blood was available in 32 patients (89%) in the titanium group and 34 patients (94%) in the carbon fibre group. No other missing values were recorded.
‡Fisher's exact test.
IQR, interquartile range; N/A, not applicable.

**Table III.** Characteristics of patients with revisions and/or complications (n = 9).

| Group | Sex, age (yrs) | Primary tumour | Fracture | Tumour location | Days to event | Implant complication | Implant switch |
|---|---|---|---|---|---|---|---|
| Titanium | M, 78 | Multiple myeloma | Pathological | Humerus | 269 | Nonunion | Yes |
| Titanium | F, 54 | Breast | Pathological | Femur | 234 | Nonunion | Yes |
| Titanium | F, 72 | Multiple myeloma | Pathological | Femur | 143 | Periprosthetic | No |
| Titanium | M, 67 | Urothelial | Impending | Femur | 17 | Periprosthetic | No |
| Titanium | M, 50 | Melanoma | Impending | Femur | 41 | Periprosthetic | No |
| Titanium | F, 51 | Breast | Pathological | Humerus | 60 | Periprosthetic | No |
| Titanium | M, 67 | Renal | Pathological | Femur | 199 | Other | Yes |
| Titanium | M, 60 | Renal | Pathological | Humerus | 62 | Recurrence around nail | Yes |
| Carbon fibre | F, 63 | Unknown | Pathological | Humerus | 222 | Nonunion | No |

**Primary outcomes.** Patients receiving carbon nails as compared to titanium nails had more blood loss (median 150 ml (IQR 100 to 250) vs 100 ml (IQR 50 to 150); p = 0.042, Mann-Whitney U test) and longer fluoroscopic time (median 150 seconds (IQR 114 to 182) vs 94 seconds (IQR 58 to 124); p = 0.001, Mann-Whitney U test). There was no difference in operating time between both groups (Table II).

**Secondary outcomes.** There were no differences between groups with regard to implant rejection, fatigue, implant exchange, postoperative complication, surgical wound infection, or mortality. Implant exchange was required in four patients in the titanium group (two for nonunion; two for local disease progression necessitating conversion to endoprosthetic reconstruction) compared to none in the carbon fibre group (p = 0.115, Fisher's exact test). Complications with implants neared statistical significance with seven patients (19%) in the titanium group, including four periprosthetic complications, versus one patient (3%) in the carbon fibre group (p = 0.055, Fisher's exact test) (Table III).

## Discussion

Based on the results of our study, carbon fibre nails used for fixation of impending or completed pathological fractures were non-inferior to titanium nails with respect to radiological union, implant failure, and short-term complications. Combined with the favourable mechanical and imaging properties of carbon fibre, our cohort's surgical and early clinical results support further consideration of carbon fibre as a suitable material for pathological lesion fixation in orthopaedic oncology when intramedullary nailing is indicated. Carbon fibre allows for visualization of healing of pathological fractures after fixation, as demonstrated in a clearly visualized healed pathological fracture of the right humerus in a 66-year-old female patient with lymphoma (Figure 2). Another example from our

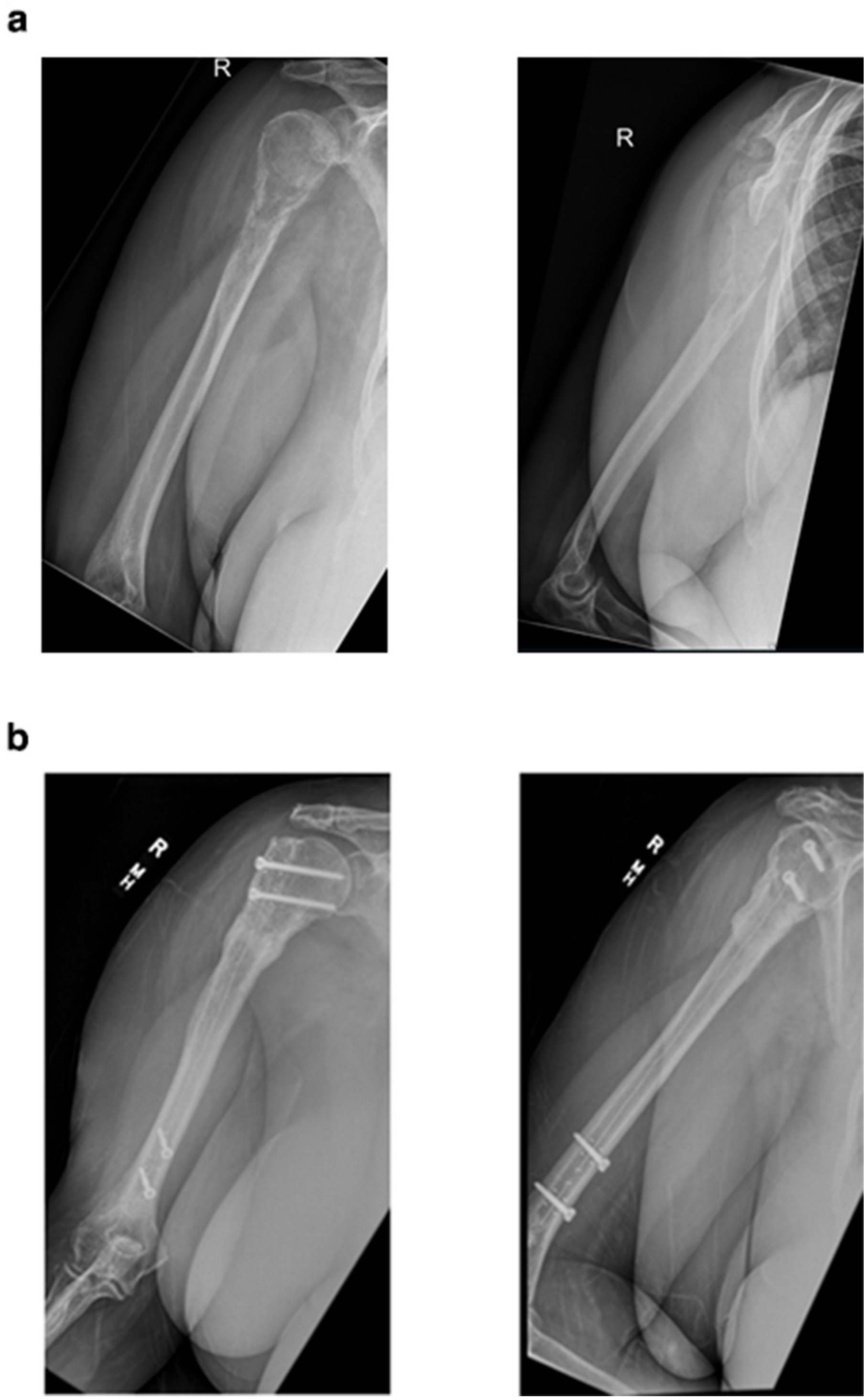


**Fig. 2**

a) Anteroposterior (AP) and lateral radiographs of the right humerus of a 66-year-old female with a pathological fracture lymphoma. b) AP and lateral radiographs of the healed right humerus at 11 months after intramedullary nail fixation with carbon fibre radiolucent implant, demonstrating its ability to allow for ongoing visualization of metastatic lesion location and healing of pathological fracture.

series demonstrates the utility of carbon fibre implants in monitoring metastatic lesions requiring prophylactic fixation. In the case of a 74-year-old female patient with metastatic breast adenocarcinoma, the radiolucency of the carbon fibre implant used in prophylactic fixation of the proximal femur allowed for improved radiation planning and monitoring of response of the metastatic lesion to radiotherapy (Figure 3). Additional advantages are


**Fig. 3**

a) Anteroposterior (AP) and lateral radiographs of the right femur of a 74-year-old female with a breast adenocarcinoma metastatic lesion noted in the proximal femur. b) AP and lateral radiographs of the right femur four months after placement of a prophylactic carbon fibre intramedullary nail. The proximal femoral lesion is visible given the radiolucency of the nail. This patient received post-surgical radiation.

the excellent biocompatibility of carbon fibre,[10] and the ability to customize the modulus of CF-PEEK during the manufacturing process to match that of cortical or cancellous bone depending on the application, all of which are particularly useful in the oncological population.

Our cohort demonstrates a favourable surgical profile of carbon fibre intramedullary nailing in both the upper and lower limbs, with a low overall complication rate. Our study was well-matched with regard to patient population demographics, and we noted a low rate of complications in both groups that did not statistically significantly differ between groups. Importantly, our study is the largest cohort in the USA concerning oncological applications of carbon fibre implants, with similar or more extensive follow-up duration and tracked patient metrics. In addition, in contrast to prior case series, we matched patients who received carbon fibre nails to those who received titanium nails. This allowed for improved ability to compare this new technology to an existing standard.[5,11]

In our comparison, we did note that estimated blood loss and fluoroscopic time were higher in the carbon fibre nail group. This may be due to relative surgeon experience with these implants, radiolucency of the implants complicating intraoperative techniques such as perfect circles for locking screw placement, or simply be due confounding due to the still relatively small number of patients in this study. Operating times were similar between groups, which may suggest a confounding effect that might not be noted until future studies using larger patient numbers are completed. We also observed that there was a longer duration of follow-up in the titanium nail group. Although patients were enrolled from the same period of time in this study, this may also play a confounding role in the observations made in this study, although patients were reassuringly matched by multiple other metrics.

There are several limitations to our study. Given the nascency of these implants, we were limited by the relatively small number of patients able to be enrolled in this study who have had carbon fibre intramedullary nail fixation thus far. Our results would be improved by follow-up studies with larger numbers of enrolled patients in a prospective manner. Although this study is one of the largest series available, as this surgical technique becomes increasingly used, future studies will likely be able to enroll greater numbers of patients for this purpose.

Our last limitation was the difficulty in comparing our results with external studies in the literature. Indeed, given the relative novelty of these implants, as well as the often highly variable nature and diverse fixation or surgical needs between patients in the orthopaedic oncological population, it is less straightforward to readily identify an appropriately comparable group from the literature. For example, in considering blood loss, operating time, and duration of fluoroscopy, these may be confounded by the nature or size of the oncological lesion. Nonetheless, when compared to existing literature, one study investigating intramedullary nailing for pathological fractures of the humerus in a cohort of 13 patients previously demonstrated a mean operating time of 92 minutes and a mean blood loss of 116 ml, both of which were comparable to our study (90 minutes and 150 ml, respectively).[12] Another prior study assessing intramedullary nailing of the femur in a group of 25 patients for impending or existing pathological fracture fixation also demonstrated similar surgical parameters, with an overall mean operating time of 104 minutes and a mean blood loss of 744 ml.[13] This study also reported that two patients in their cohort developed a wound complication, two developed pneumonia, and one patient had loss of reduction without implant failure.[13] This rate of complication is also comparable to our findings in a similarly sized cohort. Also reassuring is the fact that our study mirrors the lack of carbon fibre implant failure noted in prior studies.

In this light, our study demonstrates promising preliminary results that warrant further investigation into the application and feasibility of carbon fibre implants for pathological fracture fixation. In particular, as survival rates from cancer continue to rise,[14] it becomes increasingly important for implants to be used which afford durability and the ability for ongoing surveillance of disease progression or recurrence as well as improving ease of radiation therapy planning. Although the use of these implants in orthopaedic oncology is quite nascent, carbon fibre implants already have a track record of success in non-oncological purposes within orthopaedic surgery, particularly for fracture fixation. Steinberg et al[15] compared CF-PEEK tibial nails, proximal humeral plates, distal radius volar plates, and dynamic compression plates to current comparable commercially available titanium implants, and found they performed similarly in four-point bending tests and torsional and bending fatigue tests, while demonstrating reduced implant wear. Di Maggio et al[16] noted only one case of aseptic loosening in a series of 71 patients who underwent open reduction and internal fixation (ORIF) of the distal radius with a CFR-PEEK plate, with otherwise satisfactory functional, radiological, and clinical outcomes.

The successful track record of these implants warrants exploration of their applicability as a viable fixation option for patients with pathological fracture. In addition to increasing ease of monitoring of local disease progression or recurrence postoperatively and improving ability to assess bony healing, carbon fibre implants also help to simplify the mapping and planning of radiotherapeutic regimens, as typical titanium hardware introduces non-trivial interference with contouring precision and range calculations of radiotherapy.[17] This is due to the fact that carbon implants have radiation properties more similar to surrounding biological tissue, resulting in less radiotherapy dose perturbation than conventional titanium implants.[18,19]

One important consideration that should be assessed in future literature should be the long-term rates of revision required due to either implant failure or infection. As an inorganic material, though rates of infection might be expected to be similar to other non-biological reconstructive options, it would be important to specifically assess the propensity for bacterial biofilm formation to occur on carbon fibre implants as compared to current existing implants. With regard to implant failure, studies should evaluate whether carbon fibre implants demonstrate lower rates of periprosthetic fracture and implant failure due to their more similar modulus of elasticity compared to bone and high fatigue and bending strength, respectively. Although not necessarily specifically affecting carbon fibre intramedullary nails, one important consideration and potential limitation of carbon fibre implants more generally is that carbon fibre cannot be contoured when compared to other implants, such as stainless steel or titanium plates, which would necessitate more exacting preoperative planning or custom, patient-tailored implants. This, combined with the cost of manufacturing carbon fibre implants, would likely be the main obstacle to their widespread incorporation in orthopaedic oncology, particularly given that oncological applications rarely are one-size-fits-all.

In summary, our preliminary findings suggest carbon fibre nails may be an attractive potential alternative to titanium nails for the treatment of impending or completed pathological fractures due to metastatic bony disease. Oncological advantages favoring the use of carbon fibre implants include improved radiological properties enhancing ease of surveillance imaging and postoperative follow-up, enhanced facilitation of radiation treatment planning, and favourable biomechanical properties.

**Take home message**

- Carbon fibre nails demonstrated a non-inferior surgical and short-term clinical profile compared to titanium nails in the treatment of pathological fractures, while offering favourable material and radiological benefits advantageous in the treatment of orthopaedic oncology patients.
- Additional prospective studies are needed to better evaluate the long-term outcomes of carbon fibre nails in this population.

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- O. Q. Groot: Methodology, Formal analysis.
- N. Merchan: Methodology, Data curation.
- E. T. Newman: Methodology.
- K. A. Raskin: Methodology.
- S. A. Lozano-Calderón: Conceptualization, Data curation, Methodology, Writing – first draft, Writing – review & editing, Supervision.


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- The research described herein underwent review by our Institutional Review Board and met criteria for a waiver of informed consent (45 CFR 46.101(b)(#)).


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