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Carbon/PEEK nails: a case–control study of 22 cases

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Abstract

Background Interest around carbon/PEEK plates and nails has been raising. The elastic modulus close to the bone, the high load-carrying capacity and radiolucency make CFR/PEEK materials a potential breakthrough. In the literature, there are abundant data about CFR/PEEK plates in the treatment of proximal humerus, distal radius and distal fibula fractures. In patients affected by bone metastasis, CFR/PEEK nails were proved effective and safe with 12 months of follow-up. Very little is known about performances of CFR/PEEK nails in patients affected by other pathologies.

Purposes The aim of the study was to evaluate safety and efficacy of CFR/PEEK nails in the treatment of various pathological conditions. It was also investigated whatever radiolucency of this nails could lead to a more objective evaluation of bone callus or disease site.

Patients and methods In the study group were included 20 patients (22 bone segments) who underwent CFR/PEEK nail implantation (eight humerus, one tibia, nine femur and four knee arthrodesis). They were affected by pathological fractures, and in four cases, they required an arthrodesis of the knee. They were retrospectively evaluated considering nail failures and bone callus or disease progression (RUSH scores). Mean follow-up time was 11 months (min 6.8–max 20.3). In the control group were included patients treated with titanium nails in the same institution for the same pathologies. An interclass correlation coefficient (ICC) analysis was performed in both groups considering RUSH scores by two expert surgeon from two institution to assess whether radiolucency could lead to a more objective evaluation of disease or bone callus site.

Results The ICC of mean values between RUSH scores was 0.882 (IC 95%: 0.702–0.953) in the CFR/PEEK group, while it was 0.778 (IC 95%: 0.41–0.91) in the titanium group. Observers' evaluation showed a significantly higher obscuration by titanium nails than by CFR/PEEK nails. No osteosynthesis failures were reported in both groups.

Conclusions Our results confirm the safety of CFR/PEEK nails in the short–medium term. The radiolucency of these materials led our observers to perform more objective evaluations of bone callus formation or disease progression compared to the titanium group given the higher ICC.

Level of evidence: III Case–control therapeutic study.

Keywords Carbon · CFR/PEEK · Nail · Metastasis · Fracture healing · Bone callus

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Introduction

Interest around carbon fibre-reinforced polyetheretherketone (carbon/PEEK—CFR/PEEK) orthopaedic devices has been raising for the last two decades [7, 8, 18, 24, 25, 27]. Several theoretical advantages could be achieved using carbon/PEEK osteosynthesis plate or nails: first of all, with an appropriate manufacturing, these devices could reach an elastic modulus close to the bone and reduce stress shielding-related complications. An elastic modulus very close to the bone could also induce faster bone healing by weight-correlated stimulus to bone repair [26]. To the best of our knowledge, no data are currently available about non-union treatment by carbon/PEEK nails or plates. Furthermore, CFR/PEEK plate and nails are characterized by high load-carrying capacity and toughness [1, 4, 5]. Radiolucency is the other main advantage of this material: hence, better evaluation of bone healing or disease progression could be achieved [22, 23, 41]. In the oncological field, the interest on these devices is also raised for radiotherapy, which could be dispensed without metal backscatter effect and dose enhancement in the nearby tissues [2, 30, 40]. Recent data are showing that in the treatment of spinal tumours, carbon-derived materials can allow use of higher doses of radiotherapy with better clinical efficacy [37]. In the literature, abundant data are available about carbon/PEEK materials biomechanics and safety [11, 14, 16, 19, 20, 32, 33, 35, 38]. Recent clinical studies have already proved carbon/PEEK-derived plate to be safe and useful in the osteosynthesis of humeral, distal radius and ankle fractures [9, 21, 31, 36, 39]. Regarding CFR/PEEK femoral, humeral and tibial nails, to the best of our knowledge, only a few case reports are available to assess their clinical utility [17]. Recently, a case series about experience with CFR/PEEK nails in metastatic patients has been published by the SIOT society (Italian Society of Orthopaedics and Traumatology) [29]. In our institution, we have treated various pathological conditions with CFR/PEEK nails. The aim of our study was to evaluate whether CFR/PEEK nails could be considered non-inferior to the titanium counterparts in safety and efficacy. The other question was to understand whether the radiolucency of these osteosynthesis materials could lead to a more objective evaluation of bone callus maturation process or disease progression.

Materials and methods

Between 2014 March and 2017 October, 22 cases, 20 patients (8 males and 12 females, mean age 57 years) were treated with CFR/PEEK humeral, femoral or tibial nails (eight humeral nails, one tibial nail, nine femoral nails and

four knee arthrodesis nails) for pathological or impending fractures ($n = 13$), non-union ($n = 3$), breakage of previous osteosynthesis ($n = 1$), diaphyseal femoral fracture ($n = 1$) and knee arthrodesis ($n = 4$) (Table 1). All patients were operated by the same experienced surgeon (more than 5 years of experience in orthopaedic oncology field). The surgical technique to implant CarboFix[®] nails does not differ from the standard techniques used to implant titanium nails. The main difference affects radiolucency of carbon/PEEK materials; there are radiopaque markers around the drill holes and along the nail long axis to help positioning and drilling during the procedure. The surgeon who performed all procedures reported a short learning curve since the surgical technique did not differ much from the one used to implant titanium nails. Patients were subsequently observed for a mean of 11 months (min 6.8–max 20.3). In the study group, all patients were treated using CarboFix Piccolo (Piccolo Composite[®] nails and plates), humeral, tibial and femoral nails. We evaluated fracture healing using radiographic union score in hip fracture (RUSH) for all the districts involved (humerus, femur and tibia) and did an assessment of the image quality. A questionnaire (<http://links.lww.com/BOT/A101>) to perform a RUSH scores and image quality assessment (taken from Bhandari et al. [6]) was given to two orthopaedic surgeons with more than 10 years of experience from two different institutions; the surgeon who performed all the intervention in the study group was not involved in the assessment. These assessments were performed in single blind

Table 1 Population characteristics in study and control groups

	CFR/PEEK nails	Titanium nails
Pathological/impending fractures	13	13
Non-unions	4	4
Diaphyseal femoral fractures	1	0
Knee arthrodesis	4	2

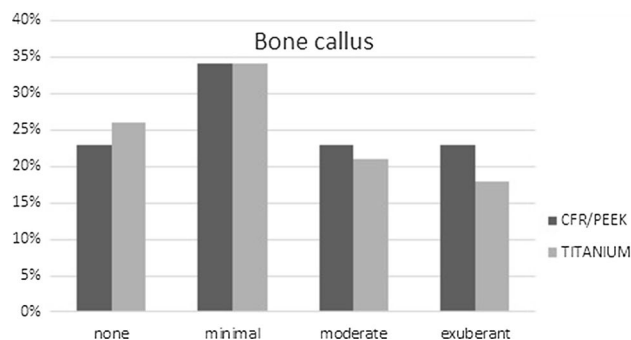


Fig. 1 Bone callus evaluation in case and control groups

and for each radiograph (AP and LL views) in both control and study groups. We made a comparison between RUSH scores obtained from our case series and 19 comparable controls (13 pathological or impending fractures, 2 knee arthrodesis, 4 non-union; Table 1) treated by intramedullary titanium nails taken from 2016–2017 database of our institution. Hardware failures and osteosynthesis complications were also compared between groups. Finally we analysed the mean radiation doses dispensed to our patients with impending and pathological fractures treated with carbon/PEEK nails and compared it with the radiation dispensed to comparable patients of the control group (age, location of metastasis, type of neoplasm) treated with titanium nails.

Statistical analysis

The scores obtained were analysed using interclass correlation (ICC, confidence interval 95%) comparing the scores of the same group (control vs cases) obtained from different observers. Complications and hardware failures were studied with Chi-square test to verify difference between groups. Mean radiation doses between cases and controls were compared using a Wilcoxon rank-sum test to assess whether patients treated by carbon nail received better radiation treatment than controls. All analyses were performed using IBM Statistic Software SPSS version 21®.

Results

The CFR/PEEK nails were comparable to the titanium nails in safety and efficacy on the short–medium term. In the study group of CFR/PEEK nails, regarding patients who were affected by non-union, each observer judged three cases as healed and one as non-healed. No hardware failure was reported in the study group. In one patient, affected by femoral diaphysis non-union, a rupture of one out of the two distal locking screws in a femoral long carbon nail was detected with no clinical consequences. In the control group of titanium nails, which included 19 subjects, for patients affected by non-union, each observer judged three cases as healed and one as non-healed (Fig. 1). No failure was reported.

The radiolucency of the CFR/PEEK nails conducted to a more objective and easier evaluation of the disease or bone callus site. In the study group, the observers stated that the image quality inhibited their assessment in 7 cases out of 44 (16%). The hardware position/placement did not inhibit their assessment in any case (0 out of 44 cases). In the control group, the image quality inhibited the observers' evaluation in 2 out of 38 cases (5%), while hardware positioning obscured fracture, disease or callus visibility in 12 out of

38 evaluations (32%). The interclass correlation coefficient (ICC) of mean values between RUSH scores performed by the observers was 0.882 (IC 95%: 0.702–0.953) in the CFR/PEEK group, while it was 0.778 (IC 95%: 0.41–0.91) in the titanium group.

No statistically significant differences between rates of hardware-related failures and complications were found using Chi-square tests. No difference was found between radiation doses dispensed in both groups. Chi-square analysis about results on fracture site obscuration by hardware materials showed a significantly higher obscuration by titanium nails than by CFR/PEEK nails ($p < 0.001$).

Discussion

Our results confirm safety and efficacy of intramedullary nailing with CFR/PEEK materials even though with a short–medium follow-up time. Safety and efficacy of CFR/PEEK-derived osteosynthesis plate have been already studied in the literature. CFR/PEEK plates in the treatment of humeral, tibial and wrist fractures appear to be as safe and useful as titanium plates. The use of carbon-derived nails has not yet been sufficiently evaluated. To the best of our knowledge, only a few case reports and a recent, large case series of CFR/PEEK nails in oncologic patients are currently available. Our case–control study included patients affected by different pathologies treated by intramedullary nailing, principally bone metastasis in oligometastatic patients. Failure rates were very low, and no differences were found between groups. Our series is not large enough to generalize these findings, but the absence of breaks stands in favour of comparable safety of carbon-derived nails referred to the titanium ones; a longer follow-up is needed to confirm the high load-carrying capacities of these materials already tested *in vitro*. Oncological patients, mostly who has bone oligometastatic pathology, are very difficult to treat [12, 13, 15]. In the subgroup of oncological patients, where very low bone healing could be expected, these materials resist mechanical failures for a mean of follow-up of 11 months. In the non-union subgroups, clinical outcomes seemed to be similar in both study and control groups, and CFR/PEEK nails did not show any detrimental effect on bone healing processes in these patients. Being the subgroup size of people affected by non-union very small, further studies are needed to confirm CFR/PEEK nail efficacy in the treatment of these pathologies. However, this small sample is one of the biggest actually available in the literature and our results could be considered as encouraging. In one case, a break of one out of two distal titanium locking screws was reported in one long nail used to treat a non-union of femoral diaphysis (Fig. 2). This break did not cause any clinical complications.



Fig. 2 Femoral shaft non-union treated by CFR/PEEK nail. Breakage of the distal screw

It is not clear whether this break could be correlated with the CFR/PEEK material interface with titanium screws.

The radiolucency of CFR/PEEK nails led to a better and more homogeneous evaluation of the disease or bone healing site by the observers. In the CFR/PEEK group, the observers stated that the hardware did not inhibit the fracture site visibility in any patient; by contrast, in the control group, hardware placement disturbed the evaluation in the 32% of the cases. This statistically significant

difference is linked to radiolucency of the nails and it was predictable (Fig. 3). These findings are supported by the interclass correlation coefficient analysis, the ICC being much higher in the study group than in the control group. Our results confirm the obvious finding that a radiolucent hardware inhibit less fracture site visibility than a radio-paque one, but they also confirm that this higher visibility leads to better agreement between experts in the bone callus evaluations. The evaluation of bone callus formation is

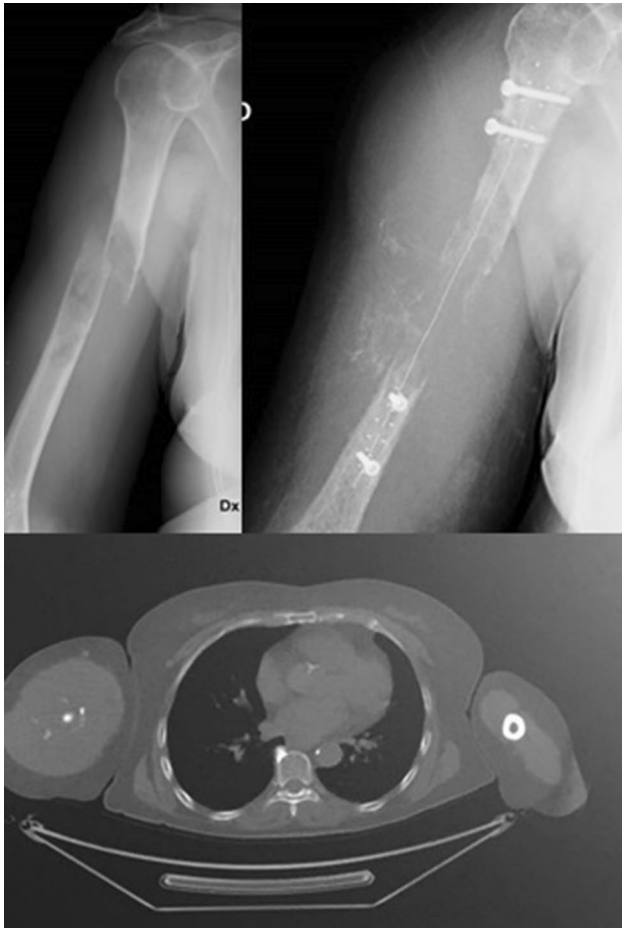


Fig. 3 Pathological fracture of the right humerus. Radiolucency of the nails and disease site visibility in the X-rays and in the CT scan images

a very difficult task and it has a maximal clinical impact. There is still lack of consensus about tools to evaluate fracture healing in an objective and reproducible manner [3, 6]. Actually, there is no fracture healing evaluation score widely used in daily clinical practice. Recent papers have evaluated RUSH and RUST scores (hip and tibial shaft fractures) as clinical tools to study fracture site with promising results [10]. These tools are not supposed to be used in the evaluation of bone healing in each bone segment. This could represent an important bias in our study planning. However, RUSH and RUST scores are the only currently available scores for the evaluation of bone callus with sufficient clinical validation [28]. The RUSH questionnaire has specific questions to assess each of the four bone cortical healing processes, to evaluate image quality and the fracture site visibility and the disturbance from the hardware. For these reasons, in our opinion, these scores were quite well adaptable to our study goals. Our results, in particular the ICC between two observers of two different institutions (Italy and Switzerland) confirms

that CFR/PEEK hardware allowed to clearly evaluate the bone callus healing process. This achievement could be very important in daily clinical practice. Decisions about the timing of weight bearing allowance and clinical judges about bone healing process progression are usually taken in a subjective manner with very high rates of discordance among doctors. This could lead to a too early or a too late concession of weight bearing with possible complications like osteosynthesis failures, articular rigidity or delay in bone healing. Disease progressions could be discovered earlier without hardware disturbance.

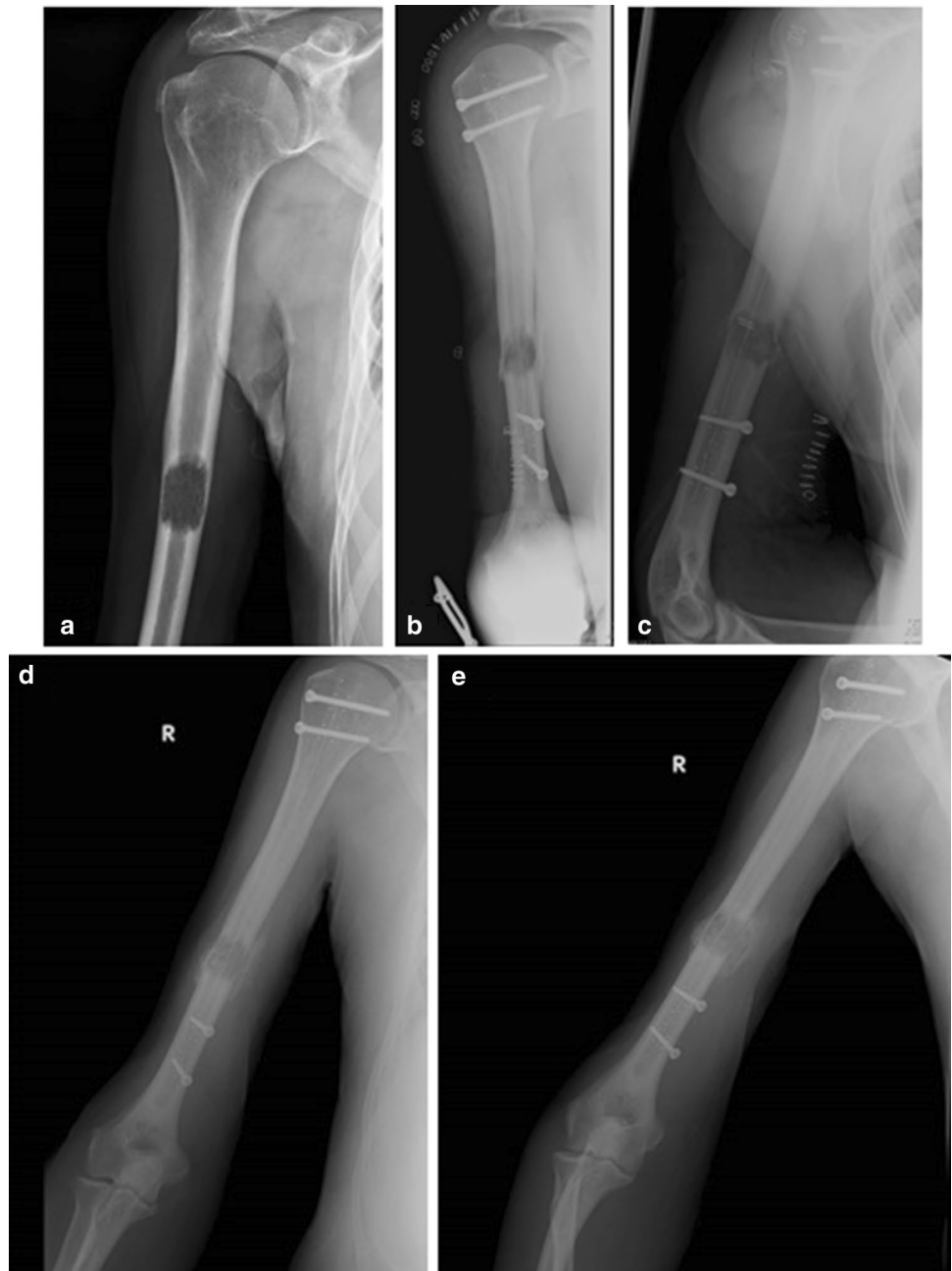
In the oncologic subgroup of patients, it is already known that a better radiation therapy with higher doses could be performed [34]. The absence of the scatter effect reduces significantly the risks of burning soft tissues near the hardware. Radiotherapists could so give higher radiation doses, and it could lead to better local control of the neoplasm. However, in our study group, radiation doses between patients treated by titanium or carbon nails did not vary. There was a lack of data about radiation therapies in both of our study and control groups. Radiotherapist of our institution did not change their management of local radiation therapies on the basis of the hardware.

An intraoperative complication occurred during implantation of a prophylactic hip nail in an impending fracture of the femoral meta-epiphysis. The distal part of a cephalic screw broke during the procedure, and the surgeon was obliged to put another shorter screw in the same tunnel of the first one because the nail has only one cephalic angle. The patient did not report any symptoms and could walk normally since the day after the procedure. The producer should improve the design of hip nails, thus allowing to put nails with different cephalic angles. A cost-effectiveness analysis should be performed to understand whether CFR/PEEK nails could become a valid alternative to titanium nails in daily clinical practice in the future. The authors' impressions confirm that the carbon nails could be an outstanding advancement mostly in the treatment of bone tumours. We should take advantage of the excellent CFR/PEEK resistance to fatigue loading, which turns out to be a very useful resource in the palliative treatment of bone metastatic tumours when there is very low expectation of bone healing. Enhanced radiotherapy could help in controlling the local disease in metastatic patients, thus allowing to have a good quality of life (Figs. 4, 5).

Conclusions

Our results are in favour of the safety of the CFR/PEEK humeral, tibial and femoral nails in the treatment of various pathological conditions in the short–medium term.

Fig. 4 Lung tumour metastasis in right humerus (**a**). Post-operative X-rays (**b, c**); post-operative X-rays at 6-month follow-up after radiotherapy (**d, e**)



The absence of failures intended as nail breakage confirms their biomechanical resistance, but a longer follow-up time is needed to confirm the load-carrying capacities of these nails. The radiolucency of these materials led our observers to perform objective evaluations of bone callus

formation or disease progression. Further studies are needed to confirm the performances of these materials in the treatment of non-unions and in the oncological patients who need adjuvant or palliative radiotherapy.

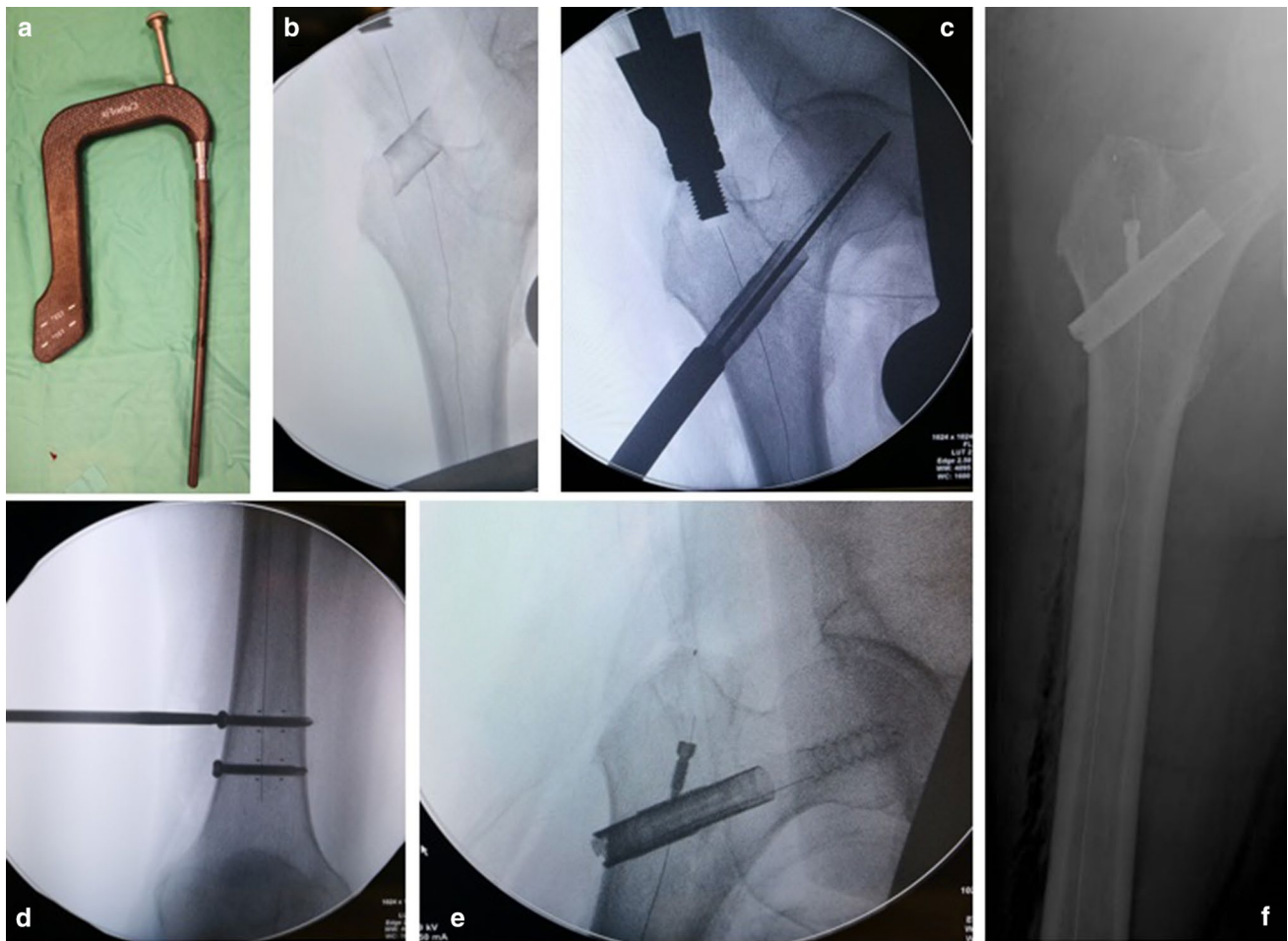


Fig. 5 Multiple myeloma metastasis in right femur. Intraoperative images showing CarboFix implant and the relative procedure (a–e); post-operative X-rays (f)

Compliance with ethical standards

Conflict of interest Each author certifies that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangements, etc.) that might pose a conflict of interest in connection with the submitted article.

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