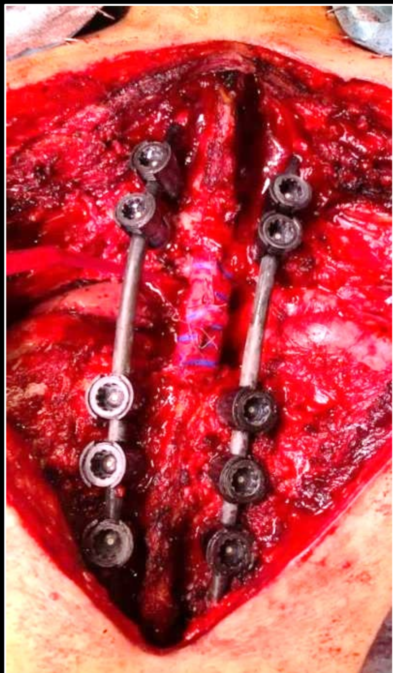
CarboClear™ Pedicle Screw System

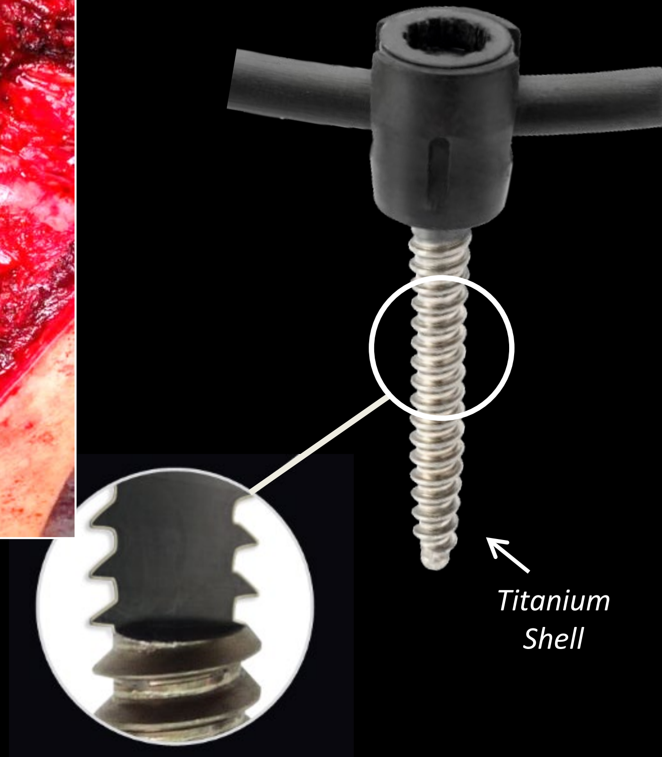
Radiation Oncologists

Short

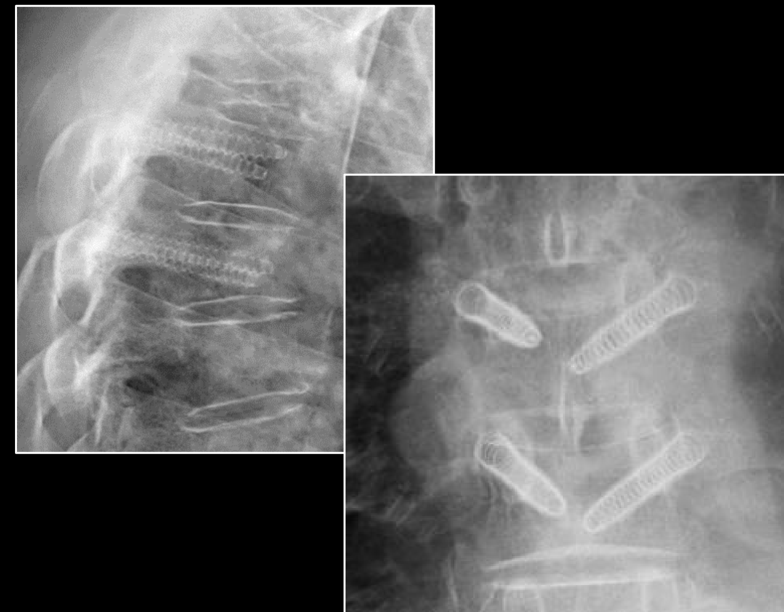
The CarboClear Pedicle Screw System



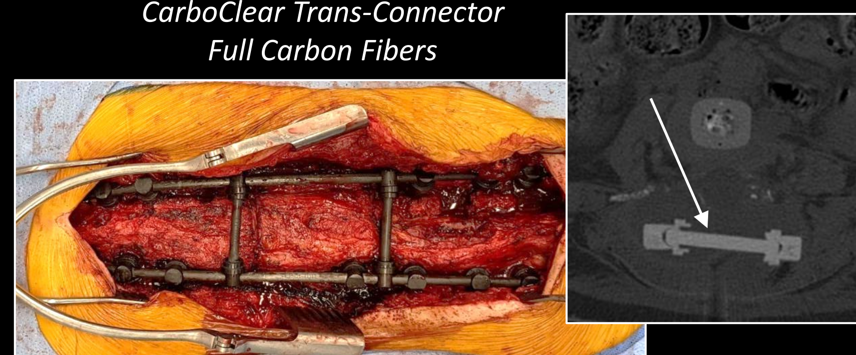
Pedicle screw & rods made of Carbon Fiber



Titanium Shell



CarboClear Trans-Connector Full Carbon Fibers



- *Ultrathin Titanium Shell for visualization & bone on growth*
- *Thickness: 50µ - No artifacts in CT & MRI*

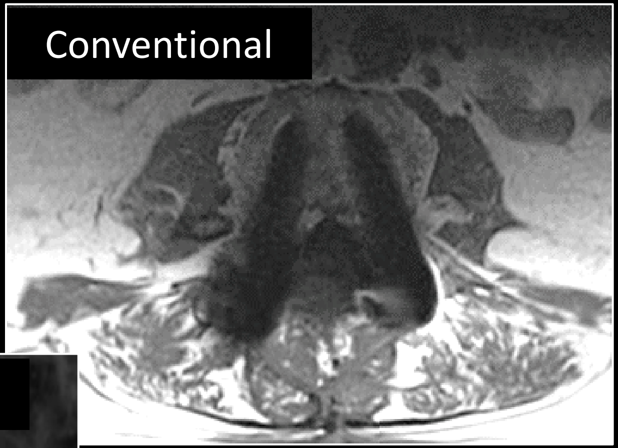
The CarboClear Pedicle Screw System

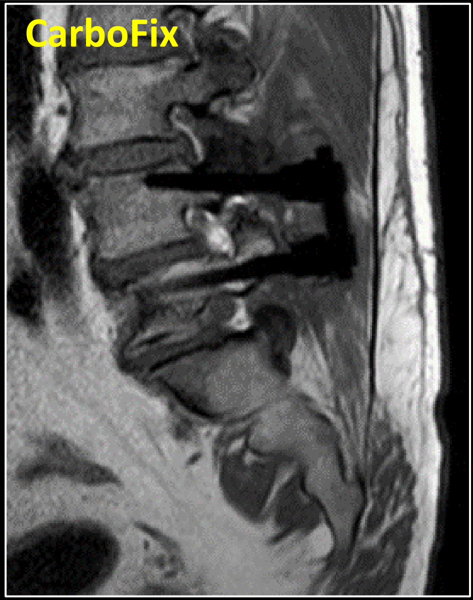
Main Advantages

- ***CT & MRI artifact free***
- ***Negligible backscattering and attenuation***
- ***Unparalleled fatigue resistance***

MRI: Artifact Free

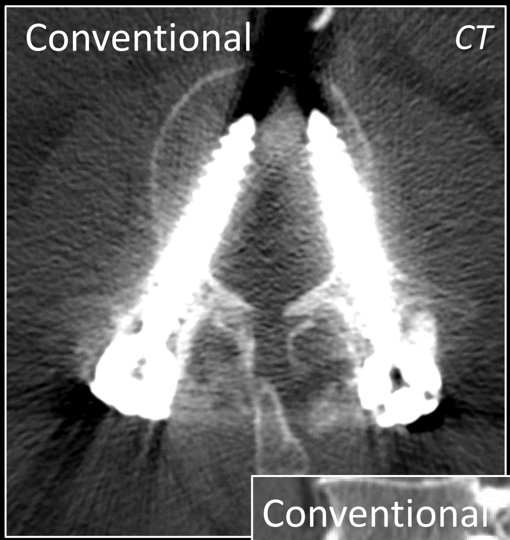
Early detection of Local Recurrency

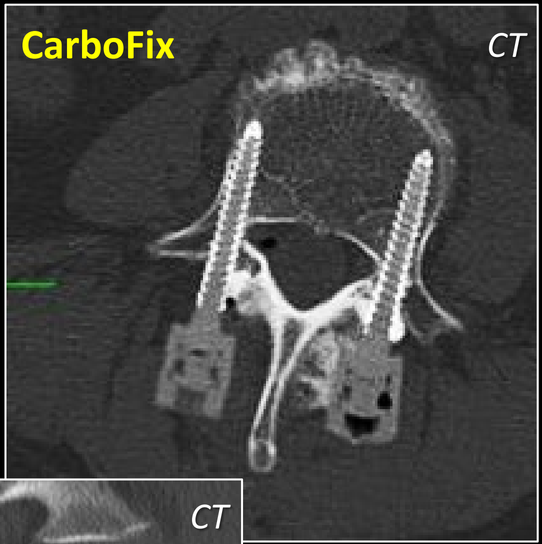


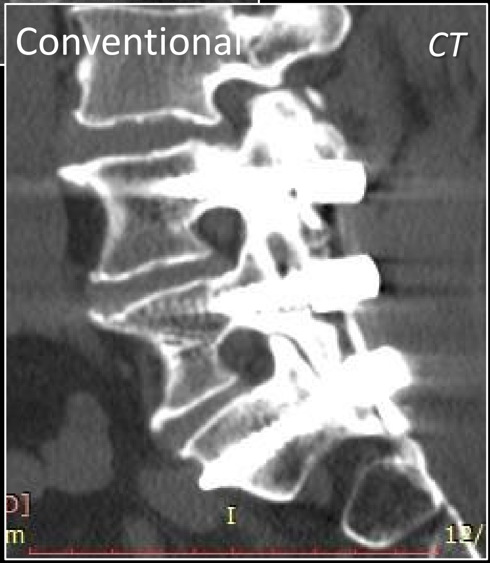


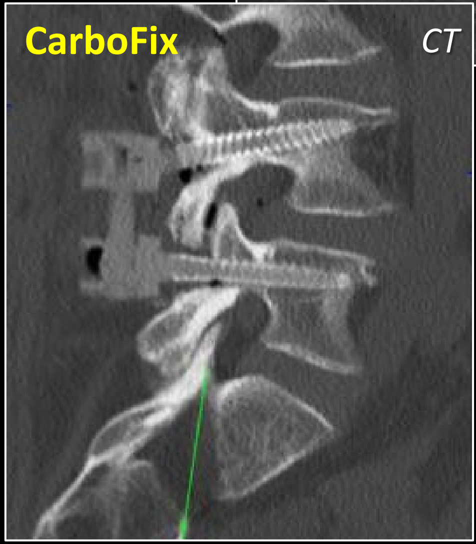
CT: Artifacts Free

Early detection of Local Recurrency & easier radiation planning









Radiation Planning

Precise delineation

Delineation

Physica Medica 44 (2017) 18–25

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Original paper

Dosimetric characterization of carbon fiber stabilization devices for post-operative particle therapy

E. Mastella[a,*], S. Molinelli[a], G. Magro[a], A. Mirandola[a], S. Russo[a], A. Vai[a], A. Mairani[a,b], K. Choi[a,c], M.R. Fiore[a], P. Fossati[a,d], F. Cuzzocrea[e], A. Gasbarrini[f], F. Benazzo[e], S. Boriani[f], F. Valvo[a], R. Orecchia[a,d], M. Ciocca[a]

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[c] University of Pavia, I-27100 Pavia, Italy
[d] IEO – European Institute of Oncology, I-20141 Milan, Italy
[e] IRCCS Foundation San Matteo Hospital, I-27100 Pavia, Italy
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A R T I C L E I N F O

Keywords:
Particle therapy
Carbon fiber orthopedic implants
CF/PEEK material
Metal artifacts
Spine tumors
Chordoma
Sarcoma

A B S T R A C T

Purpose: The aim of this 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).

Methods: 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.

Results: 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.

Conclusions: CF/PEEK spinal fixation devices resulted dosimetrically more suitable than commonly-used Ti implants for post-operative PT.

1. Introduction

Spine fixation is a surgical procedure often performed within spinal tumor treatment. If surgery alone is not oncologically appropriate, patients are eligible for post-operative adjuvant particle therapy (PT). Pencil-beam scanning (PBS) PT can offer a significant dosimetric advantage over photon beam radiation therapy (RT), due to the potential improvement in normal tissue sparing without compromising target dose coverage, even when compared to the most advanced techniques, e.g. intensity modulated RT (IMRT), volumetric modulated arc therapy (VMAT) or Tomotherapy [1]. On the other hand, range uncertainties unique for PT, if not properly mitigated, can severely compromise treatment quality. Traditional metal (high-Z) implants significantly differ from normal tissues in terms of density and composition, leading to high perturbation effects on radiation beams [2–9] and metal-related artifacts in both magnetic resonance imaging (MRI) and X-ray computed tomography (CT) [4,10,11]. In principle, the irradiation through metal implants should be avoided [2,4], especially for PT, where distortion of dose distributions and range uncertainties may compromise both disease local control and normal tissue sparing. However, this recommendation cannot always be followed when defining plan geometry, if beam direction selection is limited by dose constraints to the

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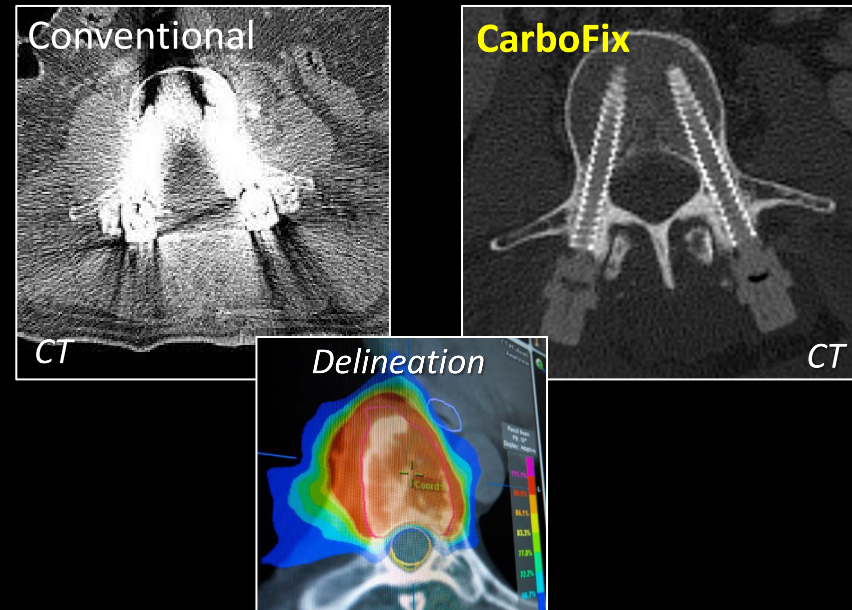


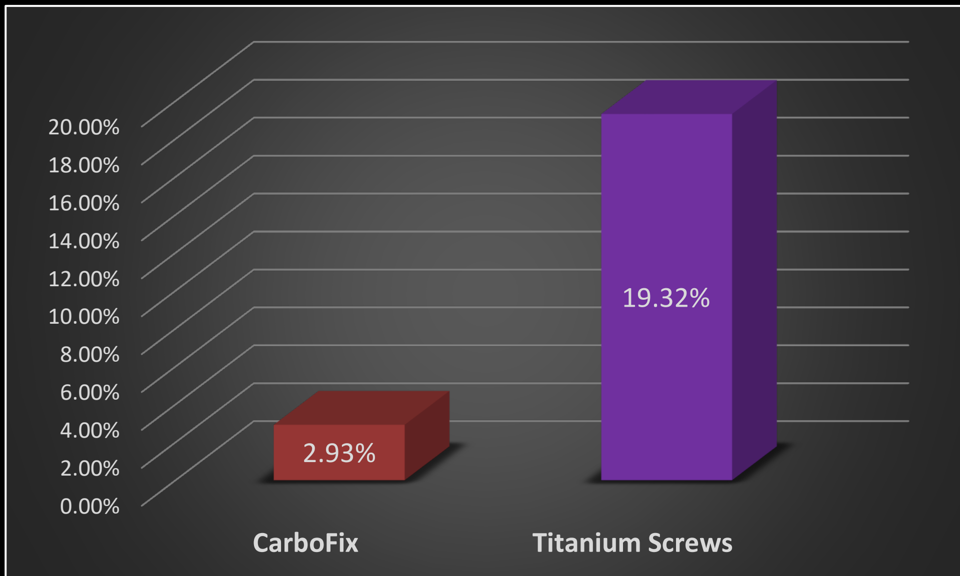
"…reduction in delineation uncertainties improve the dose calculation accuracy and treatment plan"

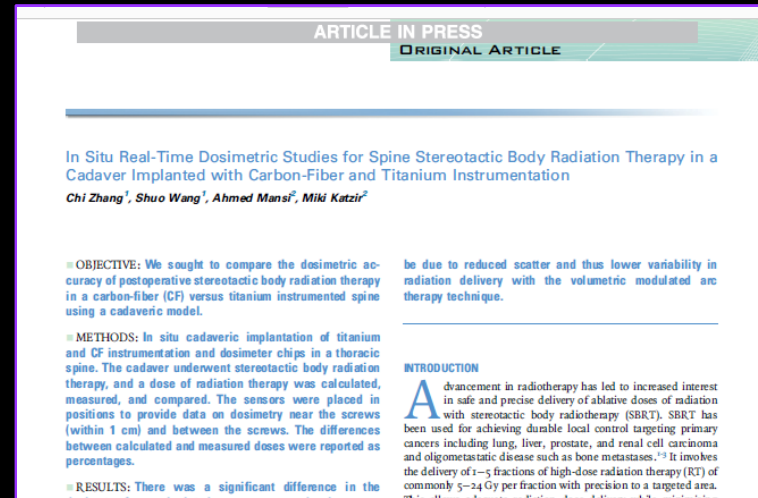
Radiation Planning

Precise Dosimetry

Katzir et al.
Departments of Radiation Oncology and Neurosurgery
University of Nebraska MC, USA

The difference (%) between Calculated & Measured Dosimetry Values





ARTICLE IN PRESS
ORIGINAL ARTICLE

In Situ Real-Time Dosimetric Studies for Spine Stereotactic Body Radiation Therapy in a Cadaver Implanted with Carbon-Fiber and Titanium Instrumentation

Chi Zhang[1], Shuo Wang[1], Ahmed Mansi[2], Miki Katzir[2]

OBJECTIVE: We sought to compare the dosimetric accuracy of postoperative stereotactic body radiation therapy in a carbon-fiber (CF) versus titanium instrumented spine using a cadaveric model.

METHODS: In situ cadaveric implantation of titanium and CF instrumentation and dosimeter chips in a thoracic spine. The cadaver underwent stereotactic body radiation therapy, and a dose of radiation therapy was calculated, measured, and compared. The sensors were placed in positions to provide data on dosimetry near the screws (within 1 cm) and between the screws. The differences between calculated and measured doses were reported as percentages.

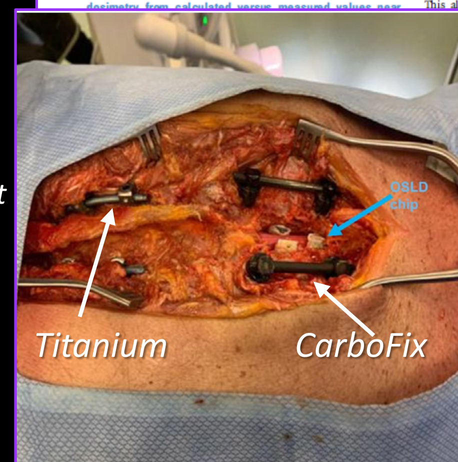
RESULTS: There was a significant difference in the

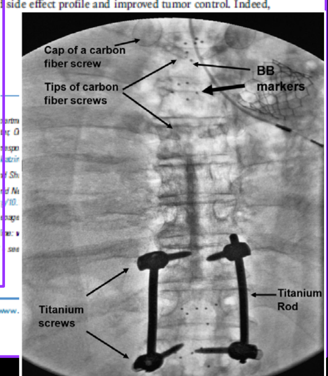
be due to reduced scatter and thus lower variability in radiation delivery with the volumetric modulated arc therapy technique.

INTRODUCTION

Advancement in radiotherapy has led to increased interest in safe and precise delivery of ablative doses of radiation with stereotactic body radiotherapy (SBRT). SBRT has been used for achieving durable local control targeting primary cancers including lung, liver, prostate, and renal cell carcinoma and oligometastatic disease such as bone metastases.[1-3] It involves the delivery of 1–5 fractions of high-dose radiation therapy (RT) of commonly 5–24 Gy per fraction with precision to a targeted area. This allows adequate radiation dose delivery while minimizing side effects associated with larger treatment fields. This arly relevant for management of spinal tumors where balance between risk of tumor progression and toxicities on therapy, particularly radiation-induced myelopathy result in paralysis. Modern radiotherapy is rapidly wing to technical advancements in advanced imaging ies, dose calculation algorithm development, and image guidance technologies, which leads to more acget delineation, precise dose calculation, and treatment ies management. These achievements allow the clinical tation of SBRT for a variety of cancers including spinal delivering high doses of radiation accurately leading to side effect profile and improved tumor control. Indeed,

WORLD NEUROSURGERY ■: e1-e6, ■ 2022



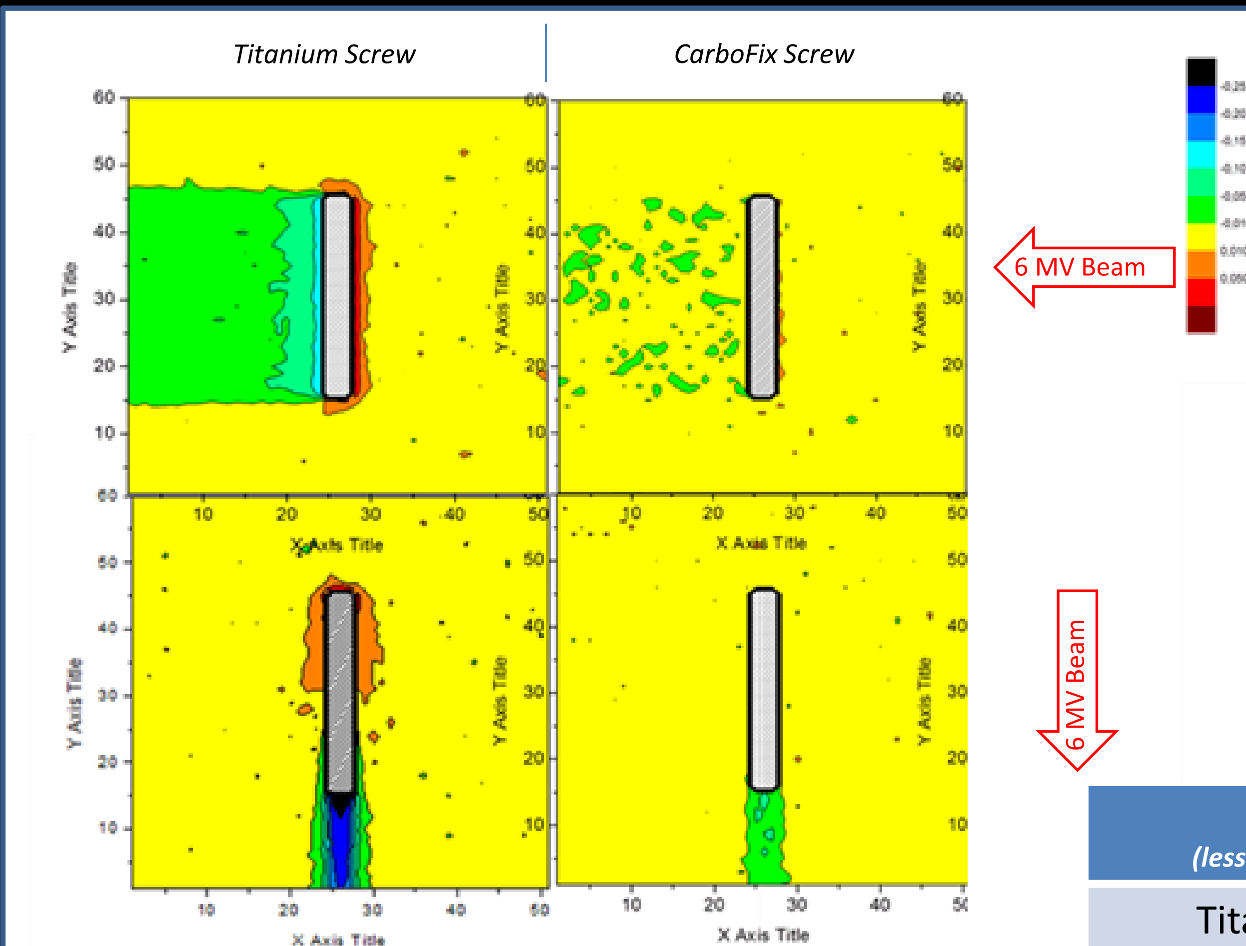


- *Dosimetry was calculated in cadaver: Titanium Construct Vs. CarboFix Construct*
- *Dosimetry measurement were performed using dosimeter chips*
- *The differences between calculated & measured dosimetry were recorded:*
  - ***Titanium Screws:** Significant difference*
  - ***CarboFix:** minor difference*
  - *Precise Dosimetry with CarboFix = Optimal radiation delivery & complication avoidance*

Negligible Backscattering & Attenuation

Negligible Backscattering & Attenuation

Perturbation



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DOI: 10.1002/acm2.12046

RADIATION ONCOLOGY PHYSICS

WILEY

Perturbation effects of the carbon fiber-PEEK screws on radiotherapy dose distribution

Alexander Nevelsky | Egor Borzov | Shahar Daniel | Raquel Bar-Deroma

Division of Oncology, Rambam Health Care Campus, Haifa, Israel

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Abstract

Radiation therapy, in conjunction with surgical implant fixation, is a common combined treatment in cases of bone metastases. However, metal implants generally used in orthopedic implants perturb radiation dose distributions. Carbon-Fiber Reinforced Polyetheretherketone (CFR-PEEK) material has been recently introduced for production of intramedullary nails and plates. The purpose of this work was to investigate the perturbation effects of the new CFR-PEEK screws on radiotherapy dose distributions and to evaluate these effects in comparison with traditional titanium screws. The investigation was performed by means of Monte Carlo (MC) simulations for a 6 MV photon beam. The project consisted of two main stages. First, a comparison of measured and MC calculated doses was performed to verify the validity of the MC simulation results for different materials. For this purpose, stainless steel, titanium, and CFR-PEEK plates of various thicknesses were used for attenuation and backscatter measurements in a solid water phantom. For the same setup, MC dose calculations were performed. Next, MC dose calculations for titanium, CFR-PEEK screws, and CFR-PEEK screws with ultrathin titanium coating were performed. For the plates, the results of our MC calculations for all materials were found to be in good agreement with the measurements. This indicates that the MC model can be used for calculation of dose perturbation effects caused by the screws. For the CFR-PEEK screws, the maximum dose perturbation was less than 5%, compared to more than 30% perturbation for the titanium screws. Ultrathin titanium coating had a negligible effect on the dose distribution. CFR-PEEK implants have good prospects for use in radiotherapy because of minimal dose alteration and the potential for more accurate treatment planning. This could favorably influence treatment efficiency and decrease possible over- and underdose of adjacent tissues. The use of such implants has potential clinical advantages in the treatment of bone metastases.

PACS
87.55.K-, 87.55.ne, 87.53.Bn

KEY WORDS
dosimetry, Monte Carlo simulations, spinal implants, spinal radiotherapy

Perturbation* *(less Backscattering & Attenuation)	
Titanium	CFR-PEEK
30%	5%

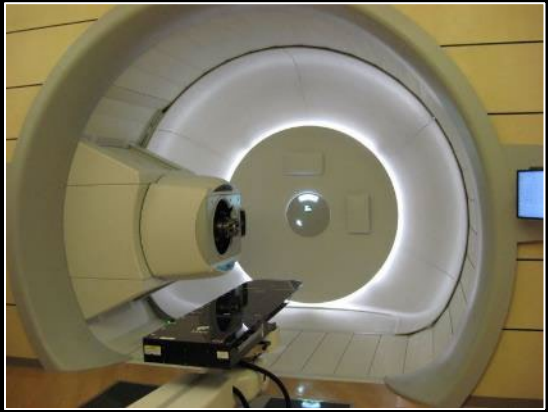
Optimal radiation delivery administration in all radiation modalities

Photon Therapy

Stereotactic Radiosurgery (SBRT/SRS)

Particle Therapy

Proton & Carbon Ion



Optimal Radiation Delivery

SBRT

Katzir et al.
Departments of Radiation Oncology and Neurosurgery
University of Nebraska MC, USA

"More accurate dosimetry and radiation therapy, as well as complication avoidance."

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ORIGINAL ARTICLE

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METHODS: In situ cadaveric implantation of titanium and CF instrumentation and dosimeter chips in a thoracic spine. The cadaver underwent stereotactic body radiation therapy, and a dose of radiation therapy was calculated, measured, and compared. The sensors were placed in positions to provide data on dosimetry near the screws (within 1 cm) and between the screws. The differences between calculated and measured doses were reported as percentages.

RESULTS: There was a significant difference in the dosimetry from calculated versus measured values near the screws of CF compared with titanium ($P = 0.0057$) with a mean percentage difference of only 2.93 for CF and a much higher value of 19.32 for titanium near the screws. There was also greater variability in the percent difference for the 2 screw types, with differences ranging from −16.54% to 35.20% near titanium screws and −3.37% to 1.66% near CF screws.

CONCLUSION: More accurate dosimetry and radiation therapy delivery with CF screws compared with traditional titanium screws may have implications on optimal radiation delivery, as well as complication avoidance. This may be due to reduced scatter and thus lower variability in radiation delivery with the volumetric modulated arc therapy technique.

INTRODUCTION

Advancement in radiotherapy has led to increased interest in safe and precise delivery of ablative doses of radiation with stereotactic body radiotherapy (SBRT). SBRT has been used for achieving durable local control targeting primary cancers including lung, liver, prostate, and renal cell carcinoma and oligometastatic disease such as bone metastases.[1-3] It involves the delivery of 1−5 fractions of high-dose radiation therapy (RT) of commonly 5−24 Gy per fraction with precision to a targeted area. This allows adequate radiation dose delivery while minimizing radiation side effects associated with larger treatment fields. This is particularly relevant for management of spinal tumors where there is a balance between risk of tumor progression and toxicities of radiation therapy, particularly radiation-induced myelopathy that may result in paralysis. Modern radiotherapy is rapidly evolving owing to technical advancements in advanced imaging technologies, dose calculation algorithm development, and real-time image guidance technologies, which leads to more accurate target delineation, precise dose calculation, and treatment uncertainties management. These achievements allow the clinical implementation of SBRT for a variety of cancers including spinal tumors, by delivering high doses of radiation accurately leading to a reduced side effect profile and improved tumor control. Indeed,

Key words
- Carbon fiber
- Instrumentation
- SBRT
- Spine oncology

Abbreviations and Acronyms
CF: Carbon fiber
CT: Computed tomography
RT: Radiation therapy
SBRT: Stereotactic body radiation therapy

From the Departments of [1]Radiation Oncology and [2]Neurosurgery, University of Nebraska Medical Center, Omaha, Nebraska, USA

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Chi Zhang and Shuo Wang are co−first authors.

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Optimal Radiation Delivery

Particle Therapy (Proton & Carbon Ion)

Particle Therapy

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Original paper

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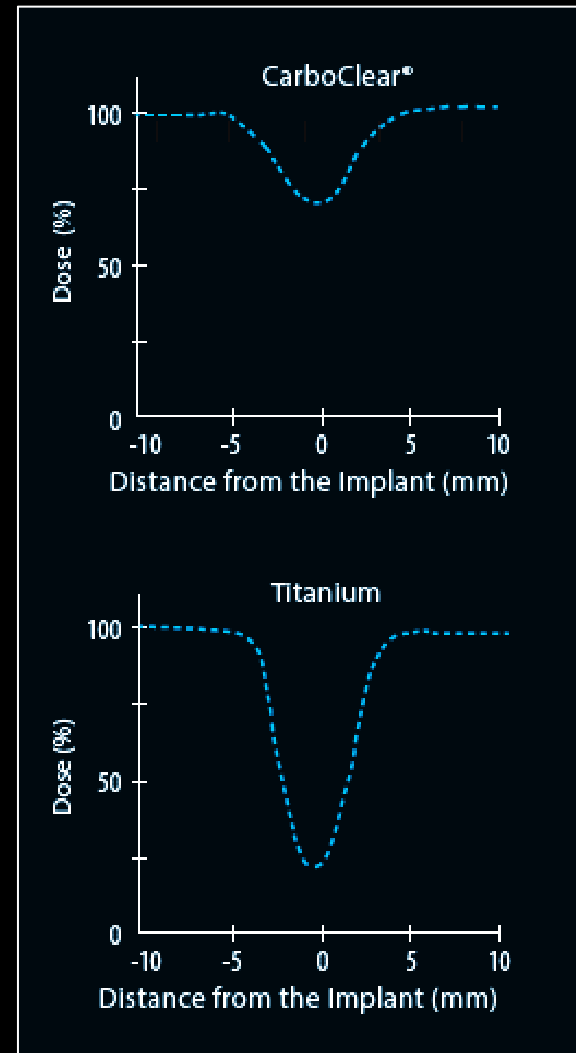

- ***Titanium Construct:*** *Up to 80% dose reduction*
- ***CarboClear Construct:*** *Up to 20% dose reduction*

Carbon Fiber:
Local Recurrence Reduction

- *Two patient Groups:*
  - *36 treated using CarboFix Pedicle Screw*
  - *42 treated using Titanium implants*
- *All suffered from metastatic lesions*
- *Mean follow-up 11-14 Months Post-Op*
- ***Local Recurrence:***
  - ***Carbon Fiber:*** *5.5%*
  - ***Titanium:*** *11.1%*

ARTICLE IN PRESS

Journal of Clinical Neuroscience xxx (xxxx) xxx

Contents lists available at ScienceDirect

Journal of Clinical Neuroscience

journal homepage: www.elsevier.com/locate/jocn

Clinical study

Carbon fiber reinforced vs titanium implants for fixation in spinal metastases: A comparative clinical study about safety and effectiveness of the new "carbon-strategy"

Fabio Cofano[a,*], Giuseppe Di Perna[a], Matteo Monticelli[a], Nicola Marengo[a], Marco Ajello[a], Marco Mammi[a], Giovanni Vercelli[a], Salvatore Petrone[a], Fulvio Tartara[b], Francesco Zenga[a], Michele Lanotte[c], Diego Garbossa[a]

[a] Department of Neuroscience "Rita Levi Montalcini", Neurosurgery Unit, University of Turin, Turin, Italy
[b] Neurosurgery Unit, Istituto Clinico Città Studi, Milan, Italy
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Keywords:
Spinal metastases
Carbon fiber screws
Carbon-fiber-reinforced PEEK
Radiotherapy
Scattering effect

ABSTRACT

In spinal oncology traditional titanium implants could significantly impair evaluation of postoperative imaging because of artifacts, potentially affecting proper planning and execution of radiotherapy and adequate radiological follow-up to rule out progression of the disease. This is why carbon fiber reinforced (CFR)-PEEK implants have been developed for spinal fixation. The advantages of this system include fewer artifacts on imaging, potentially improving the execution and quality of radiotherapy, with also a reduced scattering effect to neighboring tissues.

A comparative clinical and radiological study between new CFR-PEEK and standard titanium implants is described. Data recorded for each case included patient demographics, clinical, radiological and surgical data, intra- and postoperative complications, follow-up information. The goal of this study was to verify the safety and effectiveness of CFR-PEEK devices compared to standard titanium implants.

A total number of 78 patients were reviewed. 36 patients underwent CFR-PEEK fixation, while titanium implants were used for 42 patients. Functional recovery was obtained in both groups and registered at last follow-up in terms of axial pain and neurological status. No significant differences were found between the two groups in terms of post-operative clinical complications and hardware-related complications.

CFR-PEEK implants constitute a feasible and effective way to restore stability in metastatic spine tumors. This study found a non inferior favorable profile in terms of intraoperative and postoperative complications and functional recovery, compared to titanium. Further prospective studies are needed to clarify the potential oncological advantage of their radiolucency.

1. Introduction

In the last decades an exponential rise in the incidence of spinal metastases has been recorded and justified, above all, by the introduction of targeted therapies. The advancements in surgical techniques, radiosurgery, and immunotherapy revolutionized the treatment algorithm, enhancing the need for an essential multidisciplinary management of these patients [1–4].

Surgical indications involve the presence of instability, epidural compression and/or neurological impairment, severe axial pain, the need for diagnosis or for oncological cytoreduction or excision [1,5].

In case of overt, potential, or iatrogenic instability, fixation becomes mandatory. Traditional titanium implants have been demonstrated to possess sufficient stiffness and reliability and are currently widely used by surgeons for different pathologies involving the spine. In spinal oncology, however, titanium implants could significantly impair evaluation of postoperative imaging because of artifacts, potentially affecting proper planning and execution of radiotherapy and adequate radiological follow-up to rule out progression of disease [6].

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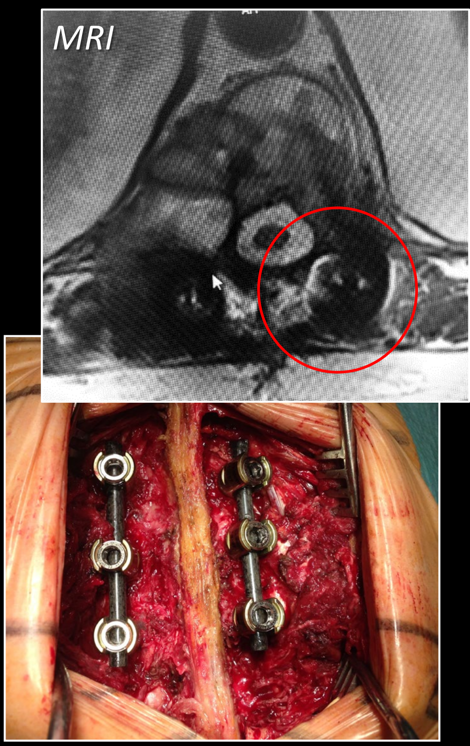
CarboClear Vs. Icotec

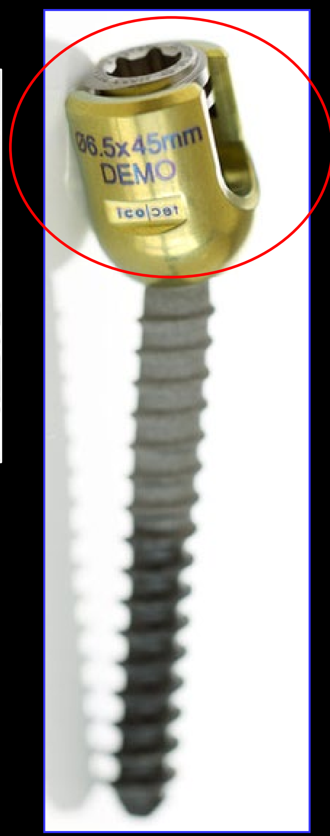
CarboClear: Full Carbon Fiber System

CarboFix	Icotec	CarboFix Advantages	Icotec Disadvantages
Full Carbon Fiber	Titanium Tulip & Set Screw	• No artifacts in CT & MRI • Easier Radiation planning • Optimal Radiation Therapy	• Artifacts in CT & MRI • Difficult Radiation planning due to Metal parts • Significant Radiation Perturbation

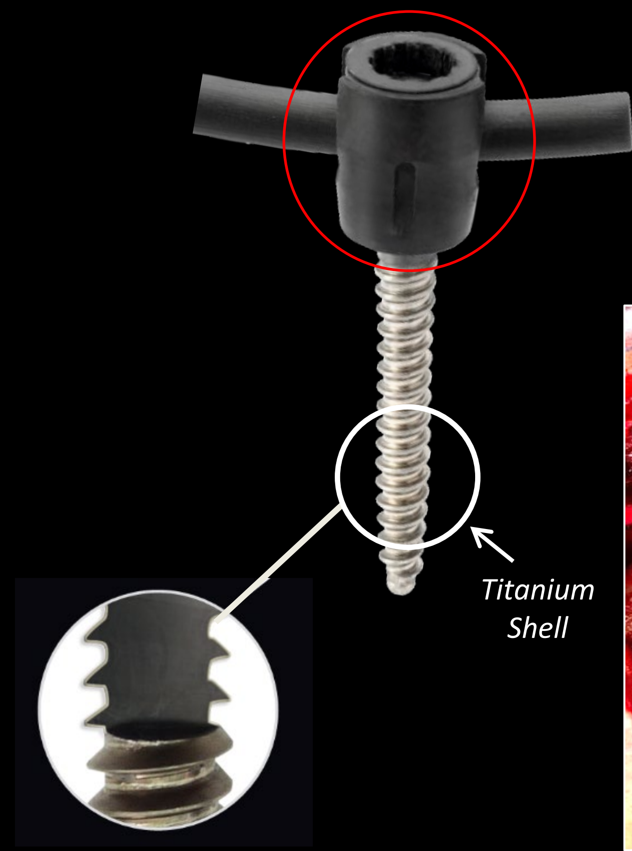
Massive Artifact



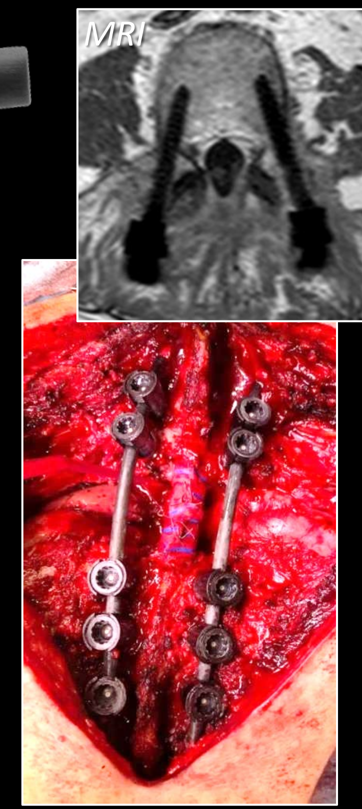
Icotec



CarboClear



No/minimal Artifact



CarboClear: Full Carbon Fiber Construct
Essential in Radiotherapy

- **CT & MRI artifact free**
  - *Early detection of Local Recurrence*
  - *Radiation Planning:*
    - *Precise Delineation*
    - *Precise Dosimetry*
    - *Reduced planning time*
- **Negligible backscattering and attenuation**
  - *Tumor receives maximum radiation with minimal collateral damage*
- **Unparalleled fatigue resistance**
  - *Enhanced construct durability*