SURGERY ON THE SPINE

Carbon/PEEK spinal implants offer new opportunities in radiation therapy of spinal tumors

BlackArmor®, a medical grade Carbon/PEEK composite material is utilized to help patients suffering from diseases such as spinal tumors. It is a combination of continuous, high-strength carbon fiber reinforced PEEK and the company's composite flow moulding (CFM) process. The result is a medical device with an interwoven 3D fiber architecture for unmatched strength.

The spine represents the most common location for metastases (Fehlings 2016). In the decision for surgical treatment, decompression of spinal structures and subsequent stabilization of the spinal column with implants is essential. The removal of the tumor will be considered in parallel. Radiation therapy is usually applied postoperatively to kill remaining cancer cells and provide pain relief.

Benefits in radiation therapy

Application of radiation therapy relies on correct CT images. The presence of state-of-the-art metal spinal implants will cause significant artifacts in the dose planning CT images (Fig. 1). Such artifacts make it much more difficult to delineate anatomic structures during the dose planning and to correctly calculate the proper dose distributions. BlackArmor is radiolucent in all diagnostic imaging modes (MRI, CT and X-ray) and will therefore not create imaging artifacts; a significant clinical benefit. It enables a precise demarcation of the tumor and planning of the doses in radiation therapy. The time-consuming manual corrections known from metallic implants are obsolete.

During radiation therapy, metal spinal implants may also shield tumor cells from the curing radiation. In addition, metal components induce scattering of the radiation beams into the surrounding soft tissue, potentially causing side effects. BlackArmor® Carbon/PEEK implants will allow the radiation beam to pass unimpeded through the material into the initially planned tumor tissue, without shielding or beam scattering. This minimizes the risk of a radiation dose that is either too high or too low and thereby protects sensitive tissue. During follow-up control for recurrent disease in peri-implant tissues, the nonmetallic BlackArmor® biomaterial also facilitates significantly better diagnostic images (CT and MRI). Recent pre-clinical radiation studies by Kashua (2016) and Gademann (2017) compared spinal constructs made of titanium versus those made of BlackArmor® Carbon/PEEK material in a radiation-oncology setup. In both studies, BlackArmor lead to a more accurate and homogenous dose planning and subsequent application of the dose with less beam scattering.

Clinical outcome data

New data (Schneider 2016) show for the first time, patients with metal implants, treated with protons have a significantly lower overall survival rate (49 percent) than those without any metal implant (66 percent).

Recently published clinical results utilizing BlackArmor® Carbon/PEEK pedicle screws in spinal tumor surgery show comparable results to metal spinal hardware, but with significantly improved imaging characteristics and suitability for radiotherapy (Eicker 2017, Ringel 2017, Choi 2017 and Hartmann 2017).

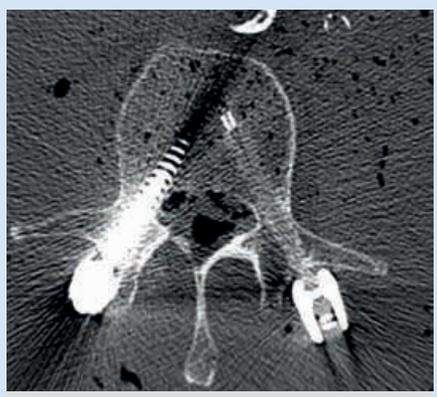

Fig. 1: Comparison of implant artifact in cadaveric model: Significant artifacts caused by titanium pedicle screw (l.), minimal artifacts with BlackArmor® pedicle screw (r.)

Fig. 2: Dose plan for radiotherapy – schematic

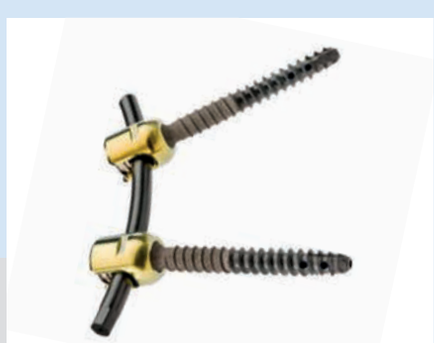

Fig. 3: VADER® Pedicle screws and rod made of BlackArmor® Carbon/PEEK material

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