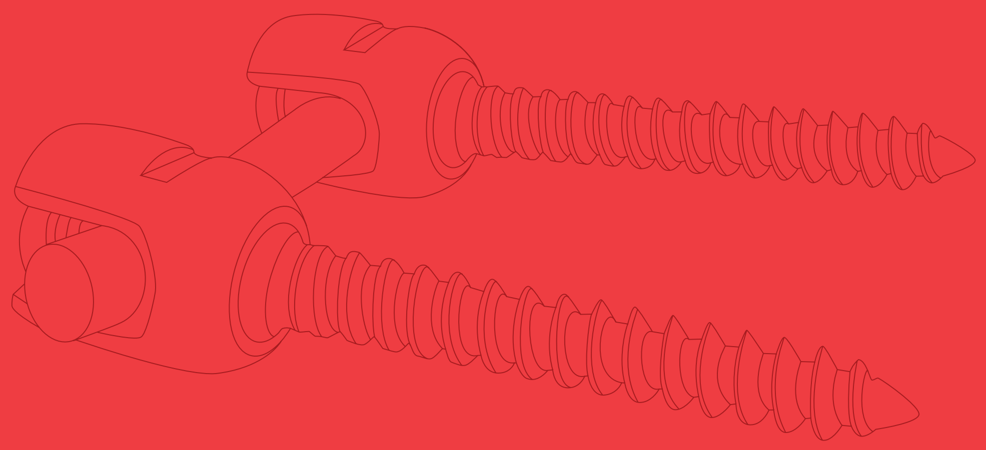
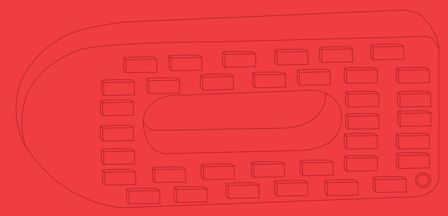
icotec

swiss quality

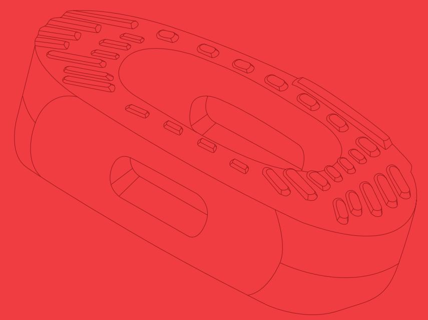
inspired by nature – built by icotec

CLINICAL STORY BOOK





inspired by nature –
built by icotec



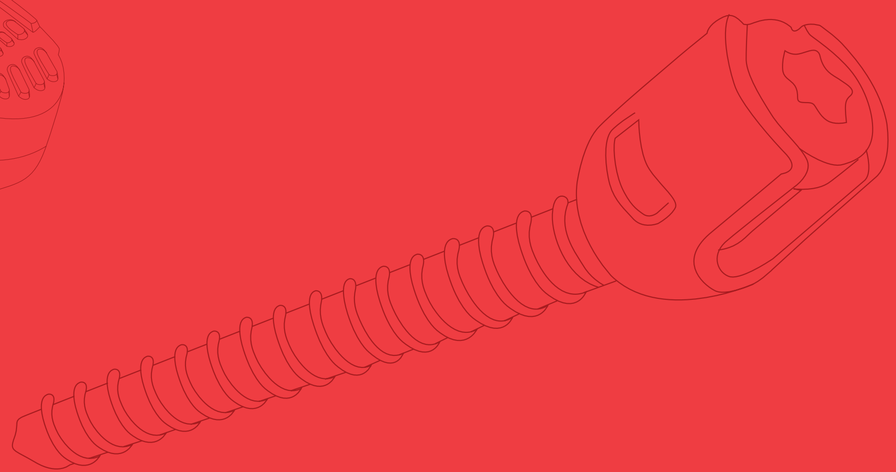


Table of Contents

Carbon/PEEK History in Orthopedics

Background of Carbon Fibers

In 1976, at the Symposium for Biomaterials in Philadelphia, Jenkins reported for the first time that the Achilles tendon in sheep could be replaced with carbon fibers. Thereafter, carbon fiber was seen very euphorically as an alloplastic ligament replacement material in various applications. Of course, there were also "misapplications" of the fibers, for example as a cruciate ligament replacement. This type of use led to massive particle formation in the knee joint and deposits in synovial fluid, cartilage, and filter organs, and consequently it failed.

- Evans reports on the reconstruction of ruptures at the extension mechanism of the knee (patellar or quadriceps tendon) which were successfully treated in the first few months or even years after the rupture (late repair) (Evans, Pritchard, and Jenkins 1987).
- Howard achieved good results in the late treatment of Achilles tendon ruptures (Howard et al. 1984).
- Strover reports on the replacement of the anterior cruciate ligament with carbon fibers. The brittle material breaks with cyclical movements and the fibers get into the joint and via the lymph system into the organs (Strover and Firer 1985; Brantigan et al. 1994).

Background of Carbon-Fiber-Reinforced PEEK (Carbon/PEEK)

The use of composites made of carbon fibers and polymers has, by contrast, achieved many successful indications. One such composite is carbon-fiber-reinforced polyetheretherketone (PEEK). PEEK (which appeared in medicine for the first time in the 1980s) acts like "glue" in the composite. On the one hand, it covers the fibers and, on the other hand, ensures that, once pressed into shape, the fibers also maintain the geometry. An important characteristic of a composite is the interaction between the fibers and the matrix ("glue"), which functions optimally in the case of the carbon fiber/PEEK system. The result is, firstly, minimal particle formation and, secondly, excellent mechanical characteristics as well as a high degree of biocompatibility.

The biocompatibility of PEEK was proven by Williams and colleagues in the first animal study in the literature (Williams D.F. 1987). Pure PEEK and carbon-fiber-reinforced samples were implanted subcutaneously in rabbits (6 months) and submuscularly in rats (30 weeks). Williams reports "minimal reaction" in both in vivo studies.

Applications of Carbon/PEEK in Endoprosthetics

Clinical trials with uncoated Carbon/PEEK femoral stems demonstrated almost total failure after 6 years, with 92% aseptic loosening (Adam et al. 2002). For long-term or fusion implants, a coating (with titanium and/or hydroxyapatite) is therefore necessary, which icotec has implemented with the VPS titanium coating (vacuum plasma spray method).

The so-called "Bradley Stem" with proximal HA coating was implanted in 65 patients from 1992 to 1998. The results have not appeared in the peer-reviewed literature. The second-generation Epoch stem from Zimmer is still being used (FDA approval 2006). The new generation of the isoelastic Mathys prosthesis, the Physiologic Stem made of PEEK-OPTIMA, has been clinically tested (Kurtz 2012).

Applications of Carbon/PEEK as a Spinal Implant

In 1991, Brantigan tested 10 cages for posterior lumbar interbody fusion (PLIF), 5 cages made of PEEK with 30% short fibers and 5 cages made of polysulfone (PSU) with 65% continuous fibers, and compared these in vitro with allograft, the standard at that time (Brantigan, Steffee, and Geiger 1991). The mechanical properties were comparable with bone (compressive strength) or even significantly better (pull-out tests), without having the risks of an allograft bone implant. The strength of the cages with continuous fibers is significantly better than with short fibers.

In 1993, Brantigan published the initial clinical outcomes with his I/F cage in the patient (Brantigan and Steffee 1993). After 2 years, all 6 patients with the I/F cage demonstrated fusion and good clinical outcomes. There were no complications associated with the cage.

Various Reviews on the Use of Carbon/PEEK in Orthopedics Are Available

The group working with Wintermantel and Mayer (Ramakrishna et al. 2001) published a comprehensive work in which they documented the use of composite materials in medical technology from 1970 to 2000.

<u>Conclusion:</u> The successful implant made of composite material will have a surface, structure, and mechanical characteristics adapted to the application and the surrounding tissue.

Hak summarizes the material characteristics and established clinical applications (Hak et al. 2014).

<u>Conclusion:</u> The good mechanical characteristics as well as the very high fatigue strength, the bone-like elastic modulus, and the radiolucency should prove in further studies that Carbon/PEEK supports callus healing – and thus can actually achieve faster and more stable fracture healing – and should clarify whether fracture reductions can be fundamentally improved with radiological imaging that is practically artifact-free. The limitations are the lack of intraoperative malleability, and in certain cases, the lack of stiffness in the fracture repair could lead to pseudarthrosis.

In his review, Kurtz (Kurtz and Devine 2007) describes the chemical, mechanical, and thermal characteristics as well as the radiation resistance and biocompatibility of PEEK in detail. The clinical applications as a trauma, spinal or femoral stem implant are clearly summarized. In particular, its use as a sliding surface in joint replacement is described; at that time it was investigated as an alternative to polyethylene, which is subject to greater degradation through gamma sterilization in an air atmosphere, resulting in a higher degree of abrasion. "Bioactive" PEEK produced by the addition of hydroxyapatite and tricalcium phosphate – which has the disadvantage of a loss of mechanical characteristics such as fracture resistance – has not been widely used to date.
<u>Conclusion:</u> PEEK had the greatest clinical influence in the area of spinal implants, and is accepted as a radiolucent alternative in the "spine community". For the "more established" fields such as artificial joint replacement and traumatology, radiolucency is an attractive but not critical feature.

The use of Carbon/PEEK as an implant material in orthopedics is highly recommended in the systematic literature analysis of Li (Li et al. 2015). Many tests have demonstrated significant benefits of Carbon/PEEK; in particular, its durability is highlighted (the fatigue characteristics under heavy loading, which is comparable with metal implants). The studies are presented clearly and in table form, separated according to biomechanical and clinical studies. Use as a sliding pair in knee prostheses is not advised, due to increased abrasion rates.

Hillock (Hillock and Howard 2014) also provides a comprehensive overview and literature analysis with references to clinical applications: cranial, maxillofacial, cervical spine, and lumbar spine and spinal imaging, humerus, distal radius, femur, hip, tibia, fibula, ankle (see also "Clinical experience with Carbon/PEEK" section).

Literature

- Adam, F., D. S. Hammer, S. Pfautsch, and K. Westermann. 2002. 'Early failure of a press-fit carbon fiber hip prosthesis with a smooth surface', J Arthroplasty, 17: 217-23.
- Brantigan, J. W., P. C. McAfee, B. W. Cunningham, H. Wang, and C. M. Orbegoso. 1994. 'Interbody lumbar fusion using a carbon fiber cage implant versus allograft bone. An investigational study in the Spanish goat', Spine (Phila Pa 1976), 19: 1436-44.
- Brantigan, J. W., and A. D. Steffee. 1993. 'A carbon fiber implant to aid interbody lumbar fusion. Two-year clinical results in the first 26 patients', Spine (Phila Pa 1976), 18: 2106-7.
- Brantigan, J. W., A. D. Steffee, and J. M. Geiger. 1991. 'A carbon fiber implant to aid interbody lumbar fusion. Mechanical testing', Spine (Phila Pa 1976), 16: S277-82.
- Evans, P. D., G. A. Pritchard, and D. H. Jenkins. 1987. 'Carbon fibre used in the late reconstruction of rupture of the extensor mechanism of the knee', Injury, 18: 57-60.
- Hak, D. J., C. Mauffrey, D. Seligson, and B. Lindeque. 2014. 'Use of carbon-fiber-reinforced composite implants in orthopedic surgery', Orthopedics, 37: 825-30.
- Hillock, R., and S. Howard. 2014. 'Utility of Carbon Fiber Implants in Orthopedic surgery: Literature review', JISRF Reconstructive Review, 4: 23-32.
- Howard, C. B., I. Winston, W. Bell, I. Mackie, and D. H. Jenkins. 1984. 'Late repair of the calcaneal tendon with carbon fibre', J Bone Joint Surg Br, 66: 206-8.
- Jenkins, D. H., I. W. Forster, B. McKibbin, and Z. A. Ralis. 1977. 'Induction of tendon and ligament formation by carbon implants', J Bone Joint Surg Br, 59: 53-7.
- Jenkins, G. M., and C. J. Grigson. 1979. 'The fabrication of artifacts out of glassy carbon and carbon-fiber-reinforced carbon for biomedical applications', J Biomed Mater Res, 13: 371-94.
- Kurtz, S. M. 2012. PEEK Biomaterials Handbook (Elsevier Inc.).
- Kurtz, S. M., and J. N. Devine. 2007. 'PEEK biomaterials in trauma, orthopedic, and spinal implants', Biomaterials, 28: 4845-69.
- Li, C. S., C. Vannabouathong, S. Sprague, and M. Bhandari. 2015. 'The Use of Carbon-Fiber-Reinforced (CFR) PEEK Material in Orthopedic Implants: A Systematic Review', Clin Med Insights Arthritis Musculoskelet Disord, 8: 33-45.
- Ramakrishna, S., J. Mayer, E. Wintermantel, and K. W. Leong. 2001. 'Biomedical applications of polymer-composite materials: a review', Composites Science and Technology, 61: 1189-224.
- Strover, A. E., and P. Firer. 1985. 'The use of carbon fiber implants in anterior cruciate ligament surgery', Clin Orthop Relat Res: 88-98.
- Williams D.F., McNamara A. 1987. 'Potential of polyetheretherketone (PEEK) and carbon-fibre-reinforced PEEK in medical applications', Journal of Materials Science Letters, 6: 188-90.

Biomechanical Properties of Carbon/PEEK

Explanation of Terms

Static strength: What is the maximum force which an implant or implant system can absorb a single time? This corresponds to the force acting on the implant if, for example, a patient with a distal radius fracture falls on the hand which was operated on soon after the surgery (a few days or weeks). In such a situation, the plate undergoes a single episode of maximum force.

Fatigue strength, dynamic strength: Fatigue strength indicates the load up to which an implant system can – in theory – be loaded an infinite number of times. This value is lower than the static strength. A familiar example is the paper clip, which can be completely bent out of shape once, but if this is repeated multiple times, it breaks. The design of the implant systems is based very heavily on this fatigue strength. Fatigue strength thus describes the strength at which the component retains its function "forever".

Stiffness of an implant system: In addition to strength, stiffness is also important. Stiffness represents how greatly an implant bends under – physiological – stress. Stiff implants bend a little, elastic implants bend a lot. A very high degree of stiffness (as in the case of metals) can lead to stress shielding and the breakdown of bone; a very low degree of stiffness or a high degree of elasticity can lead to pseudarthrosis because there is too much movement in the fracture/fusion gap during the healing process.

General

The mechanical characteristics of all composite materials are determined by the quantity, length, and orientation of the fibers in the matrix. In orthopedic applications, Carbon/PEEK materials have become established. Here a differentiation is made between short and long fibers. Short-fiber Carbon/PEEK (fiber length in the range of 1 mm) has a significantly lower strength (both static and dynamic) than material reinforced with long fibers. Typical values differ by a factor of 5 to 10 (Kurtz and Devine 2007; Hak et al. 2014).

Spine

Pedicle rods made of titanium, PEEK and Carbon/PEEK were investigated in the study by Bruner (Bruner et al. 2010).

Conclusion: The biomechanical tests do not demonstrate any statistically significant differences between the constructs (tested with 6.0 × 45 mm titanium screws) in terms of stiffness or adhesion for the lumbosacral application (single cycle test). The use of Carbon/PEEK rods is recommended, considering their radiolucency.

Trauma

Humerus (Katthagen et al. 2016):
The objective of this study was to compare the biomechanical characteristics of the Carbon/PEEK humerus plate versus the titanium humerus plate on 7 cadaver humeri in each case. For the test, titanium screws were used for both plates. The set-up of the test corresponds to that of earlier tests (Philos plate, Katthagen 2014).

Conclusion: The Carbon/PEEK plate is more elastic than the "gold standard" of the fixed-angle treatment and demonstrates significantly higher movement in the fracture area. This greater elasticity is critically judged in the paper. The fact remains, however, that the study was conducted with a humerus plate in the old design; the new plate is stiffer.

Feerick achieves comparable results in a simulation and finite-element analysis (Feerick et al. 2013).

Conclusion: The simulation with Carbon/PEEK samples predicts less tension at the transition to the bone.

Trauma implants (Steinberg et al. 2013; Hak et al. 2014):
A 10 mm tibial nail, a dynamic compression plate (DCP), a proximal humerus plate, and the volar distal radius plate were tested. Steinberg concludes that the use of carbon-fiber-reinforced PEEK for orthopedic implants offers advantages in terms of the elasticity modulus similar to bone and the ability to withstand heavy loads over the long term without failure (high level of fatigue strength).

Rohner (Rohner et al. 2005):
The Snake Plate from icotec is compared with the Synthes LCP (titanium) in an in vivo study in sheep. Six implants in each case were implanted in the sheep tibia.

Based on the results from the animal study, the use of the Carbon/PEEK Snake Plate can be recommended as an equal alternative to the titanium system, especially if close follow-up of the healing process using CT or MRI is necessary.

These Statements on Carbon/PEEK Are Substantiated by Scientific Studies (Scientific Facts)

The advantages of carbon-fiber-reinforced PEEK in the application as an orthopedic implant are the elasticity modulus similar to bone, the high degree of fatigue strength, and the characteristic of withstanding loads over the long term without failure (Steinberg et al. 2013).

Literature

- Brantigan, J. W., P. C. McAfee, B. W. Cunningham, H. Wang, and C. M. Orbegoso. 1994. 'Interbody lumbar fusion using a carbon fiber cage implant versus allograft bone. An investigational study in the Spanish goat', Spine (Phila Pa 1976), 19: 1436-44.
- Bruner, H. J., Y. Guan, N. Yoganandan, F. A. Pintar, D. J. Maiman, and M. A. Slivka. 2010. 'Biomechanics of polyaryletherketone rod composites and titanium rods for posterior lumbosacral instrumentation. Presented at the 2010 Joint Spine Section Meeting. Laboratory investigation', J Neurosurg Spine, 13: 766-72.
- Feerick, E. M., J. Kennedy, H. Mullett, D. FitzPatrick, and P. McGarry. 2013. 'Investigation of metallic and carbon fibre PEEK fracture fixation devices for three-part proximal humeral fractures', Med Eng Phys, 35: 712-22.
- Hak, D. J., C. Mauffrey, D. Seligson, and B. Lindeque. 2014. 'Use of carbon-fiber-reinforced composite implants in orthopedic surgery', Orthopedics, 37: 825-30.
- Katthagen, J. C., M. Schwarze, M. Warnhoff, C. Voigt, C. Hurschler, and H. Lill. 2016. 'Influence of plate material and screw design on stiffness and ultimate load of locked plating in osteoporotic proximal humeral fractures', Injury, 47: 617-24.
- Kurtz, S. M., and J. N. Devine. 2007. 'PEEK biomaterials in trauma, orthopedic, and spinal implants', Biomaterials, 28: 4845-69.
- Rohner, B., R. Wieling, F. Magerl, E. Schneider, and A. Steiner. 2005. 'Performance of a composite flow moulded carbon fibre reinforced osteosynthesis plate', Vet Comp Orthop Traumatol, 18: 175-82.
- Steinberg, E. L., E. Rath, A. Shlaifer, O. Chechik, E. Maman, and M. Salai. 2013. 'Carbon fiber reinforced PEEK Optima--a composite material biomechanical properties and wear/debris characteristics of CF-PEEK composites for orthopedic trauma implants', J Mech Behav Biomed Mater, 17: 221-8.

Abrasive Wear with Carbon-Fiber-Reinforced PEEK Implants

Particulate Debris and Its Formation

In general, particles always form wherever implant parts rub against each other or implants move or rub against tissue. Even micromovements are enough to generate particles.

Due to their size, geometry, and chemistry, these particles can trigger various reactions in the body, can become trapped and isolated in the body, can trigger cellular reactions (even including tumor growth), but can also be transported over long distances and deposited in tissues.

Biocompatibility of Carbon Fibers and PEEK

The very good biocompatibility of pure, uncoated carbon fibers was proven in 1982 by Tayton in an animal study with rats (Tayton, Phillips, and Ralis 1982). The biocompatibility of polyetheretherketone (PEEK) was analyzed and confirmed in the investigations by Williams (Williams D.F. 1987). BlackArmor® consists of precisely these materials: pure, uncoated carbon fibers and PEEK polymer which is classified as "medical grade" according to ASTM, and is thus suitable as implant material.

Particulate Debris and Wear of Carbon/PEEK Implants

The Carbon/PEEK trauma implants (tibial nail, dynamic compression plate (DCP), proximal humerus plate, and volar distal radius plate) investigated by Steinberg (Steinberg et al. 2013) all underwent dynamic testing of 1 million cycles. The volume of abrasion particles was determined (0.50 mm^3 Carbon/PEEK) and is lower than for titanium implants (1.19 mm^3 titanium particles).

Tullberg describes a single case (case report) of wear debris from an I/F Brantigan cage (Tullberg 1998). The Brantigan cage is a Carbon/PEEK cage, with 30% fibers of a length in the range. Fusion failed due to an infection in the segment and the cage broke due to constant loading. As a result of the persistent movement, and thus friction between the bone and the implant, there was significant formation of particles, which also dispersed into the spinal canal. Histologically, only a minor inflammatory reaction was found; in the case of the present infection, this is not necessarily related to the implant.

Togawa, in his analysis of 8 removed Carbon/PEEK cages (short fiber), also comes to similar conclusions (Togawa et al. 2004). Although more wear particles from the Carbon/PEEK cages were found in comparison with the removed titanium cages, there was no demonstrable osteolysis or inflammatory reactions which could be attributed to the debris.

Debris and Abrasive Wear of the Titanium Coating

In the case of cages and pedicle screws from icotec, in which the titanium coating is applied on Carbon/PEEK, no such effects have been observed to date. The layer meets all criteria for adhesive strength with regard to shear and tensile stress, in the static and dynamic case.

Since the titanium layer is pure titanium according to the ASTM standard, it can be assumed that the cellular reactions to wear debris from this layer can be easily compared to the reactions to conventional titanium implants and are therefore not critical.

Inflammatory Reactions to Carbon/PEEK Particles

In a case report, inflammation of the joint capsule (synovitis) 11 months after implantation of a Carbon/PEEK radius plate is reported (Merolli et al. 2016). Histopathological investigations demonstrated fibrotic granules and multicellular macrophages. The massive number of carbon fiber and PEEK particles is due to incorrect implantation or a secondary loss of reduction in the treatment and continued movement of the wrist. In addition, the surface of the implant was damaged by a steel blade (instrument set) during the surgery. The discussion from Merolli also provides a good overview of biological reactions to carbon-fiber-reinforced implants.

Clinical outcomes, Histologies

In vivo and clinical studies (Gerlach et al. 2004; Cotic et al. 2015) with osteosynthesis plates demonstrate extracellular particles but few inflammatory reactions, which would be comparable to titanium implants. In this study, Cotic confirms the results of Steinberg (Cotic et al. 2015; Steinberg et al. 2013). Cotic does not see any biological reasons for removing a Carbon/PEEK plate following healing (here: high tibial osteotomy). The small particles (< 3 micrometers, PEEK particles) do not demonstrate any cellular reaction; the large fibers are engulfed by giant cells.

Wear Debris in the Spine

Hallab compiled a review of the biological effects of abrasion particles following joint replacement in the spine (Hallab 2009). Inflammatory foreign body reactions differ from case to case, and regular follow-up after joint replacement is also highly recommended for the spine.

Another animal study by Hallab supports his hypothesis that wear debris in the intervertebral region causes fewer inflammatory reactions than abrasion of epidural implants (Hallab, Bao, and Brown 2013).

Neurotoxicity of Carbon/PEEK

Cunningham (Cunningham et al. 2013) builds on the results of Hallab. Of the 11 materials tested in mice, including PEEK, they found no indication of acute neural or systematic histopathological reactions.

Allergic Reactions

Allergic reactions to PEEK (general, not specific to abrasion particles) are very rare, but they may occur in isolated cases, as a case report shows (Maldonado-Naranjo 2015).

The Following Statements on Particulate Debris and Tissue Reactions to Carbon/PEEK Are Scientifically Proven

The biocompatibility of Carbon/PEEK is very good.

Abrasion can occur during the surgery through damage to the material or through any movements between the implants and/or tissue and cause inflammatory reactions.

Inflammatory reactions to Carbon/PEEK do not differ from those of titanium implants (Cotic et al. 2015; Gerlach et al. 2004).

icotec's Knowledge

As a supplier of Carbon/PEEK (and titanium-coated) implants, icotec must provide proof that particles from the implant material meet fundamental requirements regarding biocompatibility. This is done in investigations on particles and the associated tissue reactions in animal studies (investigation of the biocompatibility of a material according to ISO 10993, in particular section 6 "Neurotoxicity of particles"), but also using clinical cases following explantations of (temporary) implants or in the case of revisions. icotec has created a collection of data on Carbon/PEEK particles and their effects on biological tissue. In particular, the study investigating neurotoxicity provides proof that Carbon/PEEK particles, including in the area surrounding neurological structures, can be classified as a "nonirritant" (no adverse local reactions); this is particularly the case in comparison with various implant materials such as titanium, polyethylene, and others which have already had many years of clinical success (Cunningham et al. 2013). The observation period in this animal study was 13 and 26 weeks. Likewise, no accumulations of particles or changes were found in the local filter organs or distant organs such as lung, liver, kidneys, etc. (no adverse systemic reactions).

In addition, the reaction to the BlackArmor® material and its particles was investigated in a number of tissue samples, following explantation of temporary trauma implants, but also following revision or extension of spinal fusions. All samples demonstrated mild local inflammatory reactions and particles (carbon or smaller PEEK particles) which were enclosed by macrophages. In principle, the cellular reactions do not differ from those seen with titanium implants. The material and the tissue reactions can be classified as absolutely nonproblematic.

Literature

- Cotic, M., S. Vogt, S. Hinterwimmer, M. J. Feucht, J. Slotta-Huspenina, T. Schuster, and A. B. Imhoff. 2015. 'A matched-pair comparison of two different locking plates for valgus-producing medial open-wedge high tibial osteotomy: peek-carbon composite plate versus titanium plate', Knee Surg Sports Traumatol Arthrosc, 23: 2032-40.
- Cunningham, B. W., N. J. Hallab, N. Hu, and P. C. McAfee. 2013. 'Epidural application of spinal instrumentation particulate wear debris: a comprehensive evaluation of neurotoxicity using an in vivo animal model', J Neurosurg Spine, 19: 336-50.
- Gerlach, U. V., F. Magerl, B. A. Rahn, M. Werner, and R. Wieling. 2004. 'Soft tissue reaction to carbon fibre/PEEK (CF/P) osteosynthesis implants in comparison to titanium implants and to the combination of CF/P with metallic implants. An in vivo sheep study.' In Vienna Future Symposium, 19-20.
- Hallab, N. J. 2009. 'A review of the biologic effects of spine implant debris: Fact from fiction', SAS J, 3: 143-60.
- Hallab, N. J., Q. B. Bao, and T. Brown. 2013. 'Assessment of epidural versus intradiscal biocompatibility of PEEK implant debris: an in vivo rabbit model', Eur Spine J, 22: 2740-51.
- Krenn, V., P. Thomas, M. Thomsen, J. P. Kretzer, S. Usbeck, L. Scheuber, G. Perino, W. Ruther, R. v Welser, F. Hopf, and M. Huber. 2014. '[Histopathological particle algorithm. Particle identification in the synovia and the SLIM]', Z Rheumatol, 73: 639-49.
- Maldonado-Naranjo, A. L., A. T. Healy, and I. H. Kalfas. 2015. 'Polyetheretherketone (PEEK) intervertebral cage as a cause of chronic systemic allergy: a case report', Spine J, 15: e1-3.
- Merolli, A., L. Rocchi, M. De Spirito, F. Federico, A. Morini, L. Mingarelli, and F. Fanfani. 2016. 'Debris of carbon-fibers originated from a CFRP (pEEK) wrist-plate triggered a destruent synovitis in human', J Mater Sci Mater Med, 27: 50.
- Steinberg, E. L., E. Rath, A. Shlaifer, O. Chechik, E. Maman, and M. Salai. 2013. 'Carbon fiber reinforced PEEK Optima - a composite material biomechanical properties and wear/debris characteristics of CF-PEEK composites for orthopedic trauma implants', J Mech Behav Biomed Mater, 17: 221-8.
- Tayton, K., G. Phillips, and Z. Ralis. 1982. 'Long-term effects of carbon fibre on soft tissues', J Bone Joint Surg Br, 64: 112-4.
- Togawa, D., T. W. Bauer, I. H. Lieberman, and H. Sakai. 2004. 'Lumbar intervertebral body fusion cages: histological evaluation of clinically failed cages retrieved from humans', J Bone Joint Surg Am, 86-A: 70-9.
- Tullberg, T. 1998. 'Failure of a carbon fiber implant. A case report', Spine (Phila Pa 1976), 23: 1804-6.
- Williams D.F., McNamara A. 1987. 'Potential of polyetheretherketone (PEEK) and carbon-fibre-reinforced PEEK in medical applications', Journal of Materials Science Letters, 6: 188-90.

VPS Titanium Coating (Vacuum Plasma Spray Method) of Implants

PEEK is a hydrophobic material. After implantation, connective tissue encapsulation of the implant occurs; a direct osseous fusion or osseointegration does not take place as such. In this way, PEEK is extremely inert and biocompatible.

With the BlackArmor® Carbon/PEEK material from icotec the situation is virtually identical, since the carbon fibers are surrounded by PEEK. The surface of the implant is thus essentially also hydrophobic, with the consequences described above with regard to osseointegration.
For long-term implants such as spinal fusion implants, however, direct ongrowth of bone is important. Therefore, the surface must be hydrophilic, and for this, roughness is an advantage (Ra in the range of 1 to 5 µm). Both characteristics are achieved with the titanium coating, which is applied using the vacuum plasma spray method (VPS).
Very often, the literature compares titanium-coated implants with pure PEEK implants. This comparison can also be applied to BlackArmor® implants.
Devine conducted an animal study with the icotec Snake Plate as well as coated and uncoated screws. The screws were removed in vivo after 6 months and the removal torque was recorded. The VPS-coated screws had a 120% higher removal torque than the uncoated Carbon/PEEK screws (Devine et al. 2013). In an internal and therefore unpublished study, we proved, using small coated and uncoated cylinders in a canine tibia, that 6 weeks after implantation, the force needed to push out the cylinder is 25 times greater.
With all of these studies, we were able to show that the coating improves and accelerates the ingrowth or fusion behavior enormously.

These Statements on Titanium-Coated Carbon/PEEK Are Substantiated by Scientific Studies

In the animal model, the titanium plasma coating demonstrates better osseointegration after just 2 weeks in comparison to uncoated PEEK and Carbon/PEEK (Stubinger et al. 2015). This publication supports our own results. Titanium plasma coating on PEEK increases the mechanical strength in the cortical region and demonstrates histologically proven bone/implant contact in the cortical and cancellous region. In the case of uncoated PEEK implants, fibrotic connective tissue forms (animal study in sheep; Walsh et al. 2015).

Literature

- Devine, D. M., J. Hahn, R. G. Richards, H. Gruner, R. Wieling, and S. G. Pearce. 2013. 'Coating of carbon fiber-reinforced polyetheretherketone implants with titanium to improve bone apposition', J Biomed Mater Res B Appl Biomater, 101: 591-8.
- Stubinger, S., A. Drechsler, A. Burki, K. Klein, P. Kronen, and B. von Rechenberg. 2015. 'Titanium and hydroxyapatite coating of polyetheretherketone and carbon fiber-reinforced polyetheretherketone: A pilot study in sheep', J Biomed Mater Res B Appl Biomater, 104: 1182-91.
- Walsh, W. R., N. Bertollo, C. Christou, D. Schaffner, and R. J. Mobbs. 2015. 'Plasma-sprayed titanium coating to polyetheretherketone improves the bone-implant interface', Spine J, 15: 1041-9.

Advantages of Carbon/PEEK in Imaging

Introduction

The topic of imaging with Carbon/PEEK implants and their advantages compared to metallic implants hardly calls for any explanation, since it is a very evident and intuitive fact. The imaging is completely different, there are fewer artifacts, and the interpretation of biological structures is easier and clearer.

How significant the advantages are depends on the anatomic region and the indication. In the spine, the advantages in the case of tumor treatments, with the subsequent images and therapies, are more evident than in degenerative cases. This is feedback which is very often received from physicians. Nonetheless, there are users who, in a "far-sighted" approach, employ low-artifact instrumentation in degenerative cases in order to cleanly diagnose degeneration of adjacent segments or other symptoms which occur later.

Therefore, in this section, only a list of the latest or relevant literature is provided, without any discussion regarding the advantages.

In a study with 35 spinal tumor patients, Ringel investigated imaging with BlackArmor® Carbon/PEEK implants (Ringel et al. 2017). In the conclusion, he reports that with BlackArmor® Carbon/PEEK screws, the image artifacts in CT and MRI are reduced. The screws are considered to be a valid alternative for spinal stabilization, particularly in tumor patients who require postoperative imaging and radiation planning. Ringel confirms that the material has a decisive influence on the long-term outcome and survival rate of the patients.

Nevelsky et al. 2016 investigated the perturbation effects of Carbon/PEEK pedicle screws on the dose distribution in radiation therapy (using CarboFix pedicle screws). In a very simple model, they were able to determine that attenuation and backscatter effects in the case of Carbon/PEEK samples and Carbon/PEEK pedicle screws are significantly lower than with samples and pedicle screws made of titanium.

In the literature review by Stradiotti, the metal artifacts from orthopedic implants during CT and MRI are compiled (Stradiotti et al. 2009).

Conclusion: Artifacts can conceal important anatomical structures or diseases. Metal implants should optimally be oriented parallel to the main magnetic field. Good results are possible with artifact-reducing sequences and post-processing programs.

In his study, Fogel investigates the performance of computed tomography (CT) for determining bony fusion in comparison with conventional X-ray images in radiolucent cages. At the time of the investigation, a 97% fusion rate was found in 172 segments (fusion levels) (Fogel et al. 2008).

Conclusion: If conventional X-ray images with radiolucent cages demonstrate a high degree of evidence for fusion or pseudarthrosis, a spiral CT image will not provide any additional information.

As the study by Santos describes, the fusion rates are overestimated with conventional X-ray images, at 74% to 86% (depending on the method), versus controls with spiral CT at fusion rates of 65% after 5 years. The presence or absence of bony bridging can be visualized on the CTs (Santos et al. 2003).

Literature

- Ahmad, F. U., C. Sidani, R. Fourzali, and M. Y. Wang. 2013. 'Postoperative magnetic resonance imaging artifact with cobalt-chromium versus titanium spinal instrumentation: presented at the 2013 Joint Spine Section Meeting. Clinical article', J Neurosurg Spine, 19: 629-36.
- Fogel, G. R., J. S. Toohey, A. Neidre, and J. W. Brantigan. 2008. 'Fusion assessment of posterior lumbar interbody fusion using radiolucent cages: X-ray films and helical computed tomography scans compared with surgical exploration of fusion', Spine J, 8: 570-7.
- Malik, A. S., O. Boyko, N. Aktar, and W. F. Young. 2001. 'A comparative study of MR imaging profile of titanium pedicle screws', Acta Radiol, 42: 291-3.
- Nevelsky, A., Borzov, E., Daniel, S., Bar-Deroma, R. 2016. 'Perturbation effects of the carbon fiber-PEEK screws on radiotherapy dose distribution', J Appl Clin Med Phys, 18:2:62-8.
- Ringel, F., Ryang, Y.-M., Kirschke, J. S., Müller, B. S., Wilkens, J. J., Brodard, J., Combs, S. E., and Meyer, B. 2017. 'Radiolucent carbon fiber-reinforced pedicle screws for treatment of spinal tumors: advantages for radiation planning and follow-up imaging', World Neurosurg, 105: 294-301.
- Rudisch, A., C. Kremser, S. Peer, A. Kathrein, W. Judmaier, and H. Daniaux. 1998. 'Metallic artifacts in magnetic resonance imaging of patients with spinal fusion. A comparison of implant materials and imaging sequences', Spine (Phila Pa 1976), 23: 692-9.
- Santos, E. R., D. G. Goss, R. K. Morcom, and R. D. Fraser. 2003. 'Radiologic assessment of interbody fusion using carbon fiber cages', Spine (Phila Pa 1976), 28: 997-1001.
- Stradiotti, P., A. Curti, G. Castellazzi, and A. Zerbi. 2009. 'Metal-related artifacts in instrumented spine. Techniques for reducing artifacts in CT and MRI: state of the art', Eur Spine J, 18 Suppl 1: 102-8.
- Zimel, M. N., S. Hwang, E. R. Riedel, and J. H. Healey. 2015. 'Carbon fiber intramedullary nails reduce artifact in postoperative advanced imaging', Skeletal Radiol, 44: 1317-25.

Advantages of Nonmetallic Implants in Radiation Therapy

Introduction

"Surgical therapy options in the case of skeletal metastases reflect a generalized neoplastic disease. A cure is practically impossible at this stage of disease. Nevertheless, due to the very successful adjuvant and neoadjuvant chemo-, hormone, and radiation therapy as well as immunomodulation in certain tumors, survival times of several years have been achieved. This applies in particular to breast cancer and, with a somewhat limited prognosis, also to renal cell carcinoma and prostatic carcinoma. These advances have also led to surgical interventions aiming at an R0 resection in the case of solitary late metastases and given a good response to adjuvant forms of therapy. By contrast, the objective of surgical therapy at an advanced stage of disease is to preserve the patient's mobility and especially to achieve a reduction in pain. The introduction of minimally invasive surgical techniques and the development of modular, highly stable implants and prostheses mean that surgical treatments can be offered nowadays, even in the case of a poor general condition and limited life expectancy, without significant stress and risk to the patient. However, surgical therapy is only one option for the management of skeletal metastases. It is therefore absolutely essential to determine a joint therapeutic strategy together with all relevant specialist disciplines. The strategy should not only take into account the tumor-focused treatment options, but should also accommodate the patient's individual social and mental situation." (Schultheiss 2007)

Epidemiology and Etiology

The skeletal system is the third most common site of metastases, after the liver and lungs. 30% to 50% percent of all patients who develop a malignant tumor develop bone metastases. Many of these metastases do not show any symptoms, however they can be proven in post-mortem specimens.

Bone metastases occur most often in the spine (60% to 80%). Other frequently affected regions of the body (predilection sites) are the pelvis, femur, ribs, and humerus (Schultheiss 2007).

Diel and Feyer provide an informative review of the "vicious cycle" of bone destruction in bone metastases, in which the osteoclasts are activated via the tumor cells (Diel and Feyer 2011).

Effect of Metallic Implants (Titanium) on Radiation Therapy of Spinal Tumors

Verburg demonstrates the effect which titanium artifacts in CT have on the calculation of the proton dose for chordoma treatment using a phantom study and patient examinations (Verburg and Seco 2013). Metal artifacts due to titanium implants in CT significantly distort calculations of the proton dose. The range extends up to 6 mm distal of the artifact. The spatial distribution of the calculation errors significantly limits the overall success of the radiation through what is known as "passively scattered proton therapy" for chordoma.

In a phantom study, Son investigates the effect of metallic implants (titanium) on the dose calculation in radiation therapy of spinal tumors (Son, Kang, and Ryu 2012). The extent of errors caused by titanium implants is above the clinically acceptable range. It is imperative to take the distance between the titanium implant and the target or the organs at risk into account when determining the dose. Li also investigates the effect of metal implants on radiation therapy in the spine (Li et al. 2015). Metal implants have a negative effect on radiation therapy following surgical treatment of spinal tumors. There are controversies concerning the best method for determining the correct radiation dose.

Advantages of Nonmetallic Biomaterials in Radiation Therapy

A current in vitro study on cadavers compares the effect of scatter radiation in the spine (Jackson et al. 2016). Four constructs were compared: a posterior fixation without cage (control), fixation with one cage each made of PMMA, PEEK, and titanium. One construct in each case was introduced in the upper and lower part of the thoracic spine. The toxicity affecting the spinal cord is considered to be a limiting factor of the radiation dose. Scatter radiation caused by metals reduces the accuracy of the dosing, on the one hand, and can, on the other hand, unintentionally increase the effective dose (referred to as a hot spot) in the spinal cord to toxic levels. Cages made of PEEK demonstrate a statistically significant, more uniform scatter radiation in comparison to titanium or PMMA. The PEEK construct even demonstrated lower values with regard to uncontrolled scatter radiation than the construct used as a control group. This in vitro study does not permit the conclusion that a clinically significant reduction in spinal cord myelopathies (from the hot spots of the scatter radiation) or fewer symptomatic local recurrences occur due to the PEEK cages.

icotec Products

Eicker reports on the use of the BlackArmor® Carbon/PEEK pedicle system in the treatment of two groups of 5 patients diagnosed with degenerative and metastatic tumor disease respectively (Eicker et al. 2016). Artifact-free visualization of the pedicle screw is possible on both CT and MRI. The aftercare of the tumor patients is a great advantage through artifact-free imaging.

Investigations by Kashua (2016):
This study addresses the effects of different pedicle screw materials on the calculation of the dose distribution in photon and proton radiation. The basis for the creation of radiation plans is a CT data set (16-slice CT) from a phantom study on icotec BlackArmor® Carbon/PEEK and titanium screws. The beam-hardening and partial volume artifacts of the titanium screws interfere with the calculation of the dose distribution. The BlackArmor® Carbon/PEEK screws yielded artifact-free imaging which enabled homogeneous dose distribution as well as a sufficient dose in the target volume in proton as well as photon radiation.

At present, icotec is planning various studies into the effects of the implant material on the different types of radiation (photons, protons, but also hyperthermia) – in an overall picture examining the steps from analysis of the images, radiation planning, scatter radiation and thus the overall safety for the patient, the efficacy against the tumor, and reduction in toxicity on surrounding tissue. This could make it possible to break new ground in treatment. The results of these studies will be communicated on an ongoing basis.

The Following Statements Are Scientifically Proven Facts

Between 5% and 10% of all cancer patients develop spinal metastases (Bilsky et al. 1999).

Dorsal portions of the implants have little negative impact on the radiation planning; ventral portions have greater negative impact, with the risk of an increased dose to the spinal cord (Pekmezci et al. 2006).

There is no clinically acceptable range of a dose increase on critical structures caused by metal implants (Son, Kang, and Ryu 2012).

Artifacts of titanium implants generate significant errors in calculating the proton dose in tumor radiation. This leads – together with scatter radiation – to reduced efficacy in the tumor area and greater exposure of the surrounding tissue which it is important to conserve (Verburg and Seco 2013).

Literature

- Bilsky, M. H., E. Lis, J. Raizer, H. Lee, and P. Boland. 1999. 'The diagnosis and treatment of metastatic spinal tumor', Oncologist, 4: 459-69.
- Diel, I. J., and P. Feyer. 2011. 'Knochenmetastasen-Vermeidung skelettaler Komplikationen', Focus Onkologie, 14: 54-62.
- Eicker, S. O., K. Krajewski, S. Payer, T. Krätzig, and M. Dreimann. 2016. 'First experience with carbon fibers/peek pedicle screws', J Neurosurg Sci, 61: 222-4.
- Jackson, J. B., 3rd, A. Crimaldi, R. Peindl, H. J. Norton, W. E. Anderson, and J. C. Patt. 2017. 'The Effect of Polyether Ether Ketone on Therapeutic Radiation to the Spine - a Pilot Study', Spine (Phila Pa 1976), 42: E1-E7.
- Kashua, A., Schulte, T., Lehrich, P., Stöber, U., Eich, H. T., Haverkamp, U. 2016. 'Auswirkung unterschiedlicher Implantatmaterialien auf die Berechnung der Dosisverteilung', 22.Jahrestagung DEGRO, 192 Suppl. 1, 109.
- Li, J., L. Yan, J. Wang, L. Cai, and D. Hu. 2015. 'Influence of internal fixation systems on radiation therapy for spinal tumor', J Appl Clin Med Phys, 16: 5450.
- Pekmezci, M., B. Dirican, B. Yapici, M. Yazici, A. Alanay, and S. Gurdalli. 2006. 'Spinal implants and radiation therapy: the effect of various configurations of titanium implant systems in a single-level vertebral metastasis model', J Bone Joint Surg Am, 88: 1093-100.
- Schultheiss, M. 2007. 'Operative Therapieoptionen bei Skelettmetastasen', Orthopädie und Unfallchirurgie up2date, 2: 141-56.
- Son, S. H., Y. N. Kang, and M. R. Ryu. 2012. 'The effect of metallic implants on radiation therapy in spinal tumor patients with metallic spinal implants', Med Dosim, 37: 98-107.
- Verburg, J. M., and J. Seco. 2013. 'Dosimetric accuracy of proton therapy for chordoma patients with titanium implants', Med Phys, 40: 071727.

Clinical Experience with Carbon/PEEK in Traumatology

The literature review by Hillock documents the current applications of carbon fiber implants in reconstructive orthopedics (Hillock and Howard 2014). However, the review focuses here on the application and results of CarboFix Carbon/PEEK implants.

Conclusion: The very good mechanical properties of Carbon/PEEK, with its bone-like elasticity, reduce stress shielding in many applications and thus bone loss due to a lack of loading. This improves callus formation, which accordingly means a stronger bond of the fracture. The monitoring of pathological fractures in orthopedic oncology is improved by the characteristic of radiolucency. Allergic reactions are unknown to date; patients with hypersensitivity to metals can be treated.

Humerus Fracture

DiPhos H Carbon/PEEK (Schliemann et al. 2015)
Conclusion: Stabilization of the proximal humerus fracture with a Carbon/PEEK plate (DiPhos H with 30% carbon fibers) demonstrates satisfactory clinical and radiological outcomes after 2 years. The results were compared to a historical cohort (PHILOS plate) and evaluated as better. Common complications such as screw cut-out or loss of fracture reduction occurred less in the Carbon/PEEK group. The ideal treatment of a proximal humerus fracture is discussed in detail. Surgical treatment, as compared to conservative treatment, is severely limited by the unavoidable surgical complications.

Distal Radius Fracture

DiPhos Rm Carbon/PEEK (Tarallo et al. 2014)
Conclusion: The author recommends the clinical use of the Carbon/PEEK plate. One year after treatment of 40 radius fractures (type B and C, dislocated following initial reduction) with the DiPhos Rm Carbon/PEEK plate, the results were consistent with the common metal implants. The advantages over metal:

a) Bone-like elasticity reduces stress shielding
b) No cold welding between screws and plate
c) The possibility of using angle-stable and compression screws in the distal part of the plate
d) The radiolucency with the known advantage of visualization of the healing process

icotec: The Carbon/PEEK plate should be compared to a conventional titanium plate with regard to the surgical practicability and clinical outcomes (Behrendt et al. 2015)

Treatment with the Carbon/PEEK plate generally demonstrated equivalent clinical outcomes as compared to the conventional titanium plate. In the DASH and Mayo Wrist Score, moderate effects in favor of the Carbon/PEEK plate were found. After 6 weeks, both plates yielded equivalent radiological and functional outcomes. The Carbon/PEEK plate, in comparison with the conventional titanium plate, demonstrates comparable clinical-radiological outcomes with slight advantages with regard to patient satisfaction and joint mobility.

The Following Statements Are Scientifically Proven Facts

Metal implants for fracture treatment can cause intolerances in many people during cold weather. These will not occur in the case of Carbon/PEEK (Feerick et al. 2013).

Literature

- Behrendt, P., E. Kruse, T. Klüter, S. Fitschen-Oestern, M. Weuster, L. Menzdorf, J. Finn, D. Varoga, A. Seekamp, M. Müller, and S. Lippross. 2015. 'Winkelstabile karbonverstärkte Polymerkompositplatte zur Versorgung einer distalen Radiusfraktur', Der Unfallchirurg, 120: 139-46.
- Feerick, E. M., J. Kennedy, H. Mullett, D. FitzPatrick, and P. McGarry. 2013. 'Investigation of metallic and carbon fibre PEEK fracture fixation devices for three-part proximal humeral fractures', Med Eng Phys, 35: 712-22.
- Hillock, R., and S. Howard. 2014. 'Utility of Carbon Fiber Implants in Orthopedic surgery: Literature review', JISRF Reconstructive Review, 4: 23-32.
- Schliemann, B., R. Hartensuer, T. Koch, C. Theisen, M. J. Raschke, C. Kosters, and A. Weimann. 2015. 'Treatment of proximal humerus fractures with a Carbon/PEEK plate: 2-year results of a prospective study and comparison to fixation with a conventional locking plate', J Shoulder Elbow Surg, 24: 1282-8.
- Tarallo, L., R. Mugnai, R. Adani, F. Zambianchi, and F. Catani. 2014. 'A new volar plate made of carbon-fiber-reinforced polyetheretherketon for distal radius fracture: analysis of 40 cases', J Orthop Traumatol, 15: 277-83.

Clinical Experience with Carbon/PEEK in Spinal Surgery

In his literature analysis on vertebral fusion, Assem et al. describes the radiological and clinical outcomes of titanium-coated PEEK (Ti/PEEK) cages for lumbar and cervical application (Assem et al. 2015).

Conclusion: The clinical studies evaluated (n=45) demonstrate improved fusion rates of Ti/PEEK versus the uncoated cages. However, these rates are not significant; comparative studies are needed for this, on the one hand, and higher numbers of cases, on the other hand. The lack of consensus in the definition of fusion could also act as a limiting factor here.

Cervical Spine

In a multicenter, prospective, randomized study with harmonized groups (thus an extremely meaningful study design), anterior cervical discectomy and fusion, conventional and with Carbon/PEEK cage, was compared in 241 patients and 18 study centers (Groff et al. 2004).

Conclusion: The fusion rate was higher in the Carbon/PEEK group, with the same rate of complications between the two groups.

Clinical and radiological outcomes following anterior cervical discectomy in 19 patients with a Carbon/PEEK cage (Brooke et al. 1997): bony fusion was achieved in all patients. Fourteen out of 17 patients with neck pain demonstrated an improvement.

Lumbar Spine

In 1993, Brantigan published the initial clinical outcomes with his I/F cage in the patient. (Brantigan and Steffee 1993). All patients with the I/F cage demonstrated fusion and good clinical outcomes after 2 years. There were no complications associated with the cage.
Based on these results, the I/F cage received FDA approval (1999). The 10-year results in the patients treated between 1991 and 1993 were published in 2004 (Brantigan, Neidre, and Toohey 2004): clinically good to very good outcomes after 10 years in 88% of the patients. Except for one patient, fusion was able to be demonstrated in all patients who were available for radiological follow-up. In the case of the patient with unsuccessful fusion, fusion was erroneously described after 2 years.

Medacta Cage, coated vs. uncoated (Rickert 2014; Assem et al. 2015): Rickert reports on the results of a prospective randomized study (level of evidence II) with 40 patients, regarding the radiological outcomes following TLIF.

Conclusion: No radiological differences between the materials could be identified. Both cage designs demonstrate good radiological outcomes after 12 months, with fusion rates of 97%.

Clinical Outcomes with icotec Products

In a retrospective investigation in 17 patients with TLIF, Külling describes the ETurn™ Cage after 12 months (Külling F. 2013). The endpoints were fusion, sinking as well as the clinical scores SF-36 and “modified ODI”. In 8 patients, 2 or more segments were stiffened.

Conclusion: In all patients, bony fusion was achieved without any signs of radiolucent halos or sinking of the cage. Pain and function significantly improved.

Benneker retrospectively presented the radiological outcomes of treatment with titanium-coated Carbon/PEEK cages in 42 patients (47 segments) after 2 years (Benneker 2014; Assem et al. 2015). Grade 1 fusion (Bridwell) was achieved after 18 months in 94%; 6% demonstrated grade 2. Surgery of adjacent segments was necessary in 2 patients. Progression of the degeneration of adjacent segments: n=2 (4.3%).

Conclusion: The short-term results are very good. This retrospective analysis has no control group; clinical scores are missing.

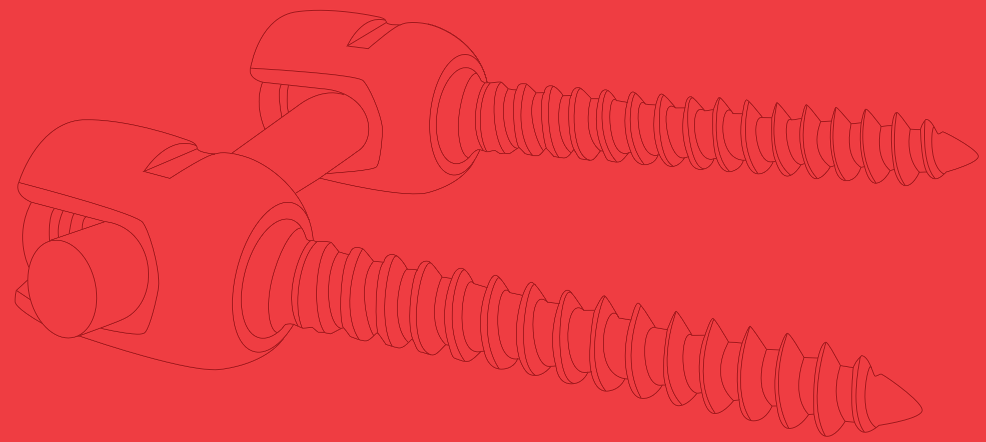
Süss presents the initial experiences with the titanium-coated BlackArmor® Carbon/PEEK screws at the 9th DWG (German Spine Conference) in Leipzig (Süss 2014). Five patients with thoracic metastases were prospectively examined clinically and radiologically (mean follow-up: 10.5 months).

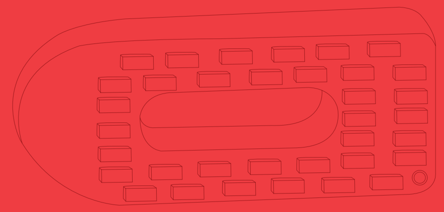
Conclusion: Good intraoperative handling, artifact-free assessment of the screw thread and transition to the bone. In comparison to the scans distorted by artifacts, it was possible to calculate the focus and dose of the radiation more precisely. Radiation dose (n = 5): 30–36 Gy. There were no screw failures and one case of suspected screw loosening without any indication for revision.

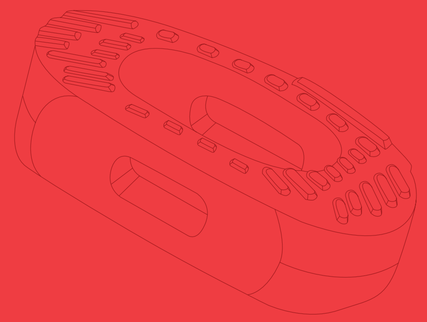
In their retrospective investigation on 16 patients with ventral stabilization, Rudez and Benneker find comparable results to metal plates, the "gold standard" (Rudez and Benneker 2014). Interbody fusion was found in all patients who underwent the 6-month follow-up examination. No loosening, failure or infection occurred. The diagnostic advantages of the artifact-free imaging using MRI, especially for neurological structures, are highlighted as a major advantage.

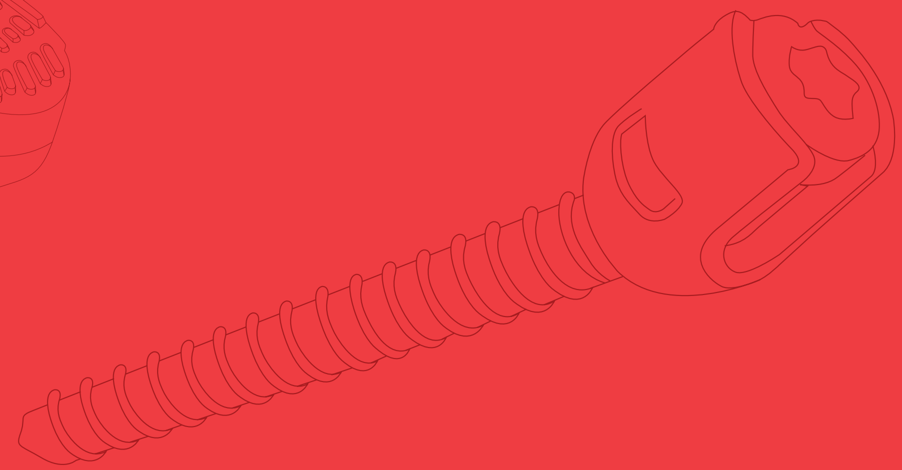
Literature

- Assem, Y., R. J. Mobbs, M. H. Pelletier, K. Phan, and W. R. Walsh. 2017. 'Radiological and clinical outcomes of novel Ti/PEEK combined spinal fusion cages: a systematic review and preclinical evaluation', Eur Spine J, 26: 593-605.
- Benneker, L.M. 2014. '2 years experiences with a new Titanium coated radiolucent TLIF cage', Eur Spine J, 23: 2521.
- Brantigan, J. W., A. Neidre, and J. S. Toohey. 2004. 'The Lumbar I/F Cage for posterior lumbar interbody fusion with the variable screw placement system: 10-year results of a Food and Drug Administration clinical trial', Spine J, 4: 681-8.
- Brantigan, J. W., and A. D. Steffee. 1993. 'A carbon fiber implant to aid interbody lumbar fusion. Two-year clinical results in the first 26 patients', Spine (Phila Pa 1976), 18: 2106-7.
- Brooke, N. S., A. W. Rorke, A. T. King, and R. W. Gullan. 1997. 'Preliminary experience of carbon fibre cage prostheses for treatment of cervical spine disorders', Br J Neurosurg, 11: 221-7.
- Groff, M. W., C. Lauryssen, J. W. Brantigan, D. H. Kim, D. A. Wiles, M. O'Brien, and F. Albanna. 2004. 'A prospective, randomized, multicenter evaluation of a carbon fiber reinforced polymer (CFRP) cage for anterior cervical discectomy and fusion', Cervical Spine Research Society. Boston, Paper #46.
- Külling F., Krebs J., Aebli N., Forster T. 2013. 'Radiologic and Clinical Outcome of TLIF using CF/PEEK Cages coated with Titanium', Neuroradiology, 55: 789-90.
- Rickert, M. 2014. 'Randomized evaluation of bone ingrowth after intervertebral body fusion with a PEEK and a Titanium coated PEEK TLIF oblique cage. Radiological outcome after 12 months', Eur Spine J, 23: 2475-76.
- Rudez, J., and L. M. Benneker. 2016. 'First clinical experience with a carbon/peek composite plating system for anterior stabilization of the cervical spine', Orthopaedic Proceedings, 98B: Supp. 3: 139.
- Süss, O. 2014. 'First clinical experience with titanium-coated carbonfiber PEEK screws in spinal tumor surgery', Eur Spine J, 23: 2572.









CE 0297

icotec ag

Industriestrasse 12
9450 Altstätten
Switzerland
Phone: +41 71 757 00 00
Fax: +41 71 757 00 01
info@icotec.ch
www.icotec-medical.com

0189EN.2019-02

swiss quality