Supercritical CO_2 machining of Titanium; a potential game changer

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INTRODUCTION: The effects of supercritical CO_2 cooling (Sc-CO_2) on the high-speed milling of titanium grade 5 (Ti6Al4V) using a Mikron MILL S 400 U® 5-axis milling machine, equipped with a StepTec 42k spindle, and a Fusion Coolant Systems Pure-Cut+® Sc-CO_2 delivery system was studied at various cutting parameters and compared with flood coolant milling using emulsion. The effects on tool wear, achievable MRR, surface roughness and micro-hardness were evaluated.

METHODS: The experiments were divided into five steps each with different cutting parameters where cutting speed (Vc) was varied from 110 to 200 m/min. A new tool was used continuously for each Sc-CO_2+MQL (minimum quantity lubrication; 2 ml/min of medical grade oil) and emulsion from step 1 up to step 4. The main aim was to analyse the achievable material removal rate for both coolant systems. At step 5 a high volume of material (113,850 mm^3) was machined using new tools (for both Sc-CO_2+MQL and emulsion) to assess the tool life and machining performance in detail.

RESULTS: At the end of each test step, the tool wear progression was monitored; no significant differences could be detected up to the step 4 of the tests. However, after Step 4, the cutting edges and rake faces of the tools show significant differences. The emulsion tool was severely damaged. In contrast, the CO_2 tool edges are not damaged as severely and the tool can still continue cutting.

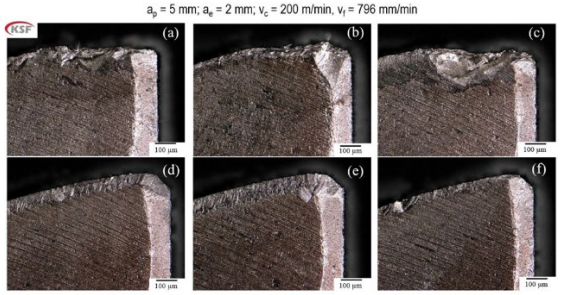

Fig. 1: Tool wear (rake faces) under traditional flood coolant (top 3 images a -c) and using sc-CO_2 (lower 3 images, d-f).

The represented differences between the cutting forces (Fy) of the emulsion tool and Sc-CO_2 tool were analysed during step 5 of the machining process and confirms the higher performance of sc-CO_2. Indeed, the cutting forces induced by the Sc-CO_2 tool are constant during the long time material removal and much lower than the emulsion tool in all performed machining passes, becoming much more prominent (up to 65% lower) when the 45th pass of the machining process was accomplished, indicating much higher tool wear rate for the emulsion tool.

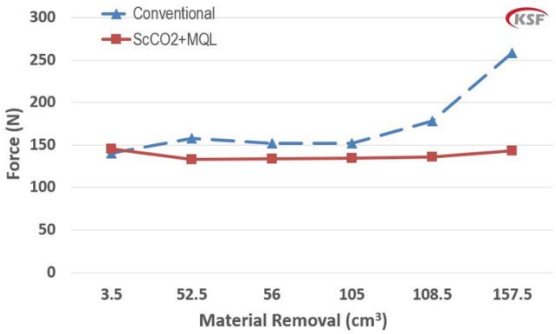

Fig. 2: Cutting Force vs. Material Removal

Additional measurements were taken comparing burr formation, surface roughness and surface micro-hardness - all showed benefits to the use of sc-CO_2 as a coolant.

DISCUSSION & CONCLUSIONS: The results of the tests conducted showed that, as compared to flood coolant milling, the use of Sc-CO_2 milling led to:

- reliable machining at significantly higher Material Removal Rates (MRR)
- significantly increased tool life (up to over 100 %)
- significantly lower cutting forces (up to 50 %)
- increased surface micro-hardness (up to 30 %)
- reduced surface roughness (up to 50 %)

We believe this technology has the potential to improve machining efficiency, reduce the pollution and energy consumption (through reduction or elimination of washing to remove emulsion), improve mechanical properties of the machined material, and reduce the risk to patients (through the reduced risk of contamination from residual cutting fluids).

Direct Part Laser Marking in the Medtech Industry – How to make UDI-Code Marking Safe and Compliant

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INTRODUCTION: Manufacturers of medical instruments or implants are currently challenged with increasing requirements regarding the UDI (Unique Device Identification) of their products. Each product has to be centrally registered and officially certified, but it also needs to bear an individual UDI-code which makes each product traceable throughout its entire life cycle.

METHODS: A UDI-code consists of a human and a machine-readable part in form and content, so that it matches the requirements of the FDA and the MDR. A UDI also needs to be applied directly on the surface of a medical product, it is used and processed multiple times. To fulfil these requirements, manufacturers need to integrate an appropriate marking procedure in their production process. A laser marking system can ensure the durability and legibility of a UDI-code which is necessary for product traceability.
What makes a laser marking process safe and compliant? FOBA offers an innovative three-step marking workflow which includes pre-mark validation of the product, automated mark alignment, even if the product is placed at a random position within the marking field, and a post-mark validation of quality, content and position of the markings.
The so called “Medical Plug-in” is a software which helps medical device manufacturers to implement a safe and secure UDI-marking process for its validation.

RESULTS: The main goal of the UDI system is to enhance patient safety by means of medical device traceability. In the case of product recalls, it is possible to track every single part from its manufacturing until the use on the patient.
Considering implants, a UDI also facilitates the registration into centralized implant databases e.g. EUDAMED or GUDID. This also results in better implant quality control. A UDI also helps to streamline part processing in manufacturing or in the hospital cleaning and sterilization procedures.

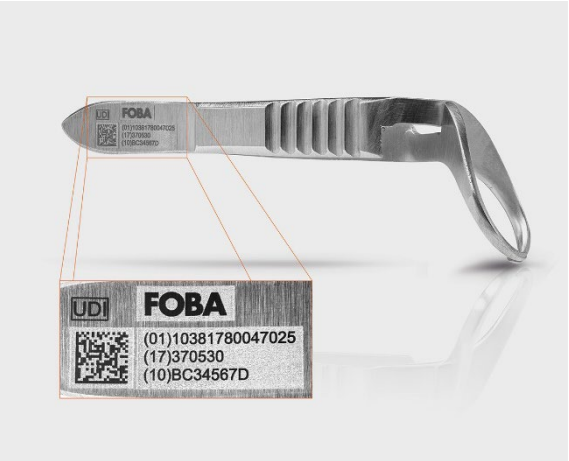

Fig. 1: Medical clamp with laser marked UDI code: To improve the readability of the code and characters, the laser created a white background (frosting).

DISCUSSION & CONCLUSIONS: The process of finding the appropriate laser marking parameters for a specific material can be tedious and time consuming. In most cases these are trial and error processes. The goal is to share the knowledge of key parameters to create a safe and secure UDI marking process.
The FOBA application team has developed innovative solutions out of 12 independent variables such as laser source, the optic used and the desired final effect to create the best laser marking results. In this way the operator receives the optimum laser parameters for lasting and secure UDI laser marks.

REFERENCES: Case Study: RUDOLF Medical - Lasers as the standard of the future for the marking of surgical scissors and instruments (https://www.fobalaser.com/applications/case-studies/rudolf-medical/).

Medical Industry White Paper - Unique Device Identification (UDI) Requirements, deadlines, secure labelling according to FDA and MDR (https://www.fobalaser.com/applications/case-studies/udi-whitepaper/).

In-silico comparison of topology-optimized acromion Levy type II implants

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INTRODUCTION: Acromion Levy type II fractures following reverse shoulder arthroplasties (RSA) are an exemplary indication showing the complicated elaboration of suitable implant designs due to various superimposed loading scenarios. Literature shows that only few studies are available investigating the true cause of why such fractures occur. In addition, no specific implant designs exist to treat these fractures specifically. This project aims to explain, in form of a conceptual (qualitative) structure mechanical in-silico investigation, why acromion Levy type II fractures occur, how modern design tools can be used to develop suitable implants and how these perform compared to a lateral clavicle plate (LCP).

METHODS: A digital 3D cortical bone model, based on the CT data of an 83-years old female patient, was developed for a shoulder complex consisting of scapula and clavicle. Literature-reconstructed muscle force vectors of the anterior, middle and posterior deltoid muscle [1] were used to setup a patient-specific finite-element model describing the biomechanical behaviour for abduction and flexion in the range of 15° to 120°. Automated parametrization studies were performed to analyse angle-specific stresses and deformations in the Levy type II area. Sensitivity analyses were used to investigate the sensitivity of resulting parameters upon changes in the magnitude, orientation and origin of muscle force vectors. After the identification of critical loading scenarios, the setup for the development of topologically optimized implant designs was elaborated. With the help of current movement studies, all investigated abduction and flexion angles were weighted according to their frequency of occurrence throughout the day. Through an iterative approach, while continuously simplifying the model and varying optimization constraints, final implant designs were generated for a preventive (pre-Levy II fracture) and curative (post-Levy II fracture) treatment, following an RSA. The final implant designs were benchmarked against an LCP.

RESULTS & DISCUSSION: The simulation studies revealed locations of potentially critical equivalent stresses below the acromion arc and maximum principal stresses on the superior-anterior border on the acromion, which may promote the start of a Levy type II fracture. The sensitivity analyses showed that equivalent stresses below the acromion arc significantly increased for abduction and flexion if vectors are increasingly directed in inferior or anterior orientation. This increased the resulting bending and torsional moments in the Levy type II area. An anteriorization of the shoulder joint centre revealed the most significant equivalent stress increase below the acromion arc. The final benchmarking of topologically optimized implant solutions against an LCP revealed better performance, mainly convincing through an improved anatomical fit, a better mass exploitation and more homogeneous stress distributions (*Fig. 1*) may leading to an advantageous fatigue life behaviour.

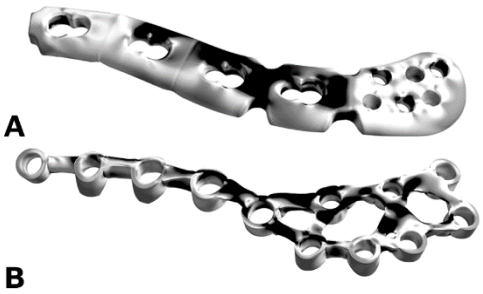

Fig. 1: Qualitative comparison of most critical (=black) equivalent stress distributions during post-operative abduction at 65° for a standard LCP (A) and a topology-optimized solution (B).

CONCLUSIONS: Finite-element analyses and topology optimizations are powerful tools for the analysis of complex biomechanics. Nevertheless, performing valuable topology optimizations in the field of biomechanics requires a detailed understanding of the method, as well as validated models to deliver usable outputs.

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Duplex technology to improve osteointegration of PEEK implants

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INTRODUCTION: PEEK is widely used in medical fixation devices for orthopaedic, cranio-maxillary, spinal and trauma implants. The main advantage of PEEK is its Young's modulus, close to that of a human bone. Moreover, PEEK is extremely strong, durable, highly resistant to creep and fatigue, it withstands sterilization, and is radiolucent. The only disadvantage of PEEK is that it is a bioinert material with a highly hydrophobic surface, resulting in poor cytocompatibility and insufficient osteointegration.

The aim of this study is to develop a surface treatment to improve osteointegration of PEEK implants. In partnership with the company Nano Bridging Molecules SA (NBM), an innovative duplex surface treatment was developed combining Atomic Layer Deposition (ALD) technology and multi-phosphonate functionalization by dip coating (commercialised as SurfLink™ by NBM). Multi-phosphonates are used to improve osseointegration and long-term success of dental implants [1]. The proposed method showed promising results, a hydrophilic surface with a conformal coverage and increased cytocompatibility with osteoblast cells.

METHODS: First, a titanium dioxide layer is deposited by ALD on PEEK, followed by a multi-phosphonate layer (SurfLink™, NBM) deposited by dip coating. The SurfLink™ coating is known to improve the osteointegration of titanium surfaces. Cell inseminations are done on 3D printed (A) bare PEEK and the same PEEK coated with (B) TiO_2-ALD and (C) TiO_2-ALD-SurfLink™. Two different osteoblastic lines were used, SaOS and HOS, over a period of 2 weeks. Three independent experiments in triplicate were performed.

RESULTS: It was noticed that a minimum TiO_2-ALD layer thickness of 50 nm is crucial for achieving a high coverage of the multi-phosphonate coating (SurfLink™).

After 10 days of seeding, an increase by a factor of 1.2-1.4 in cell proliferation was observed on the coated PEEK samples as compared to a bare PEEK (Fig. 1).

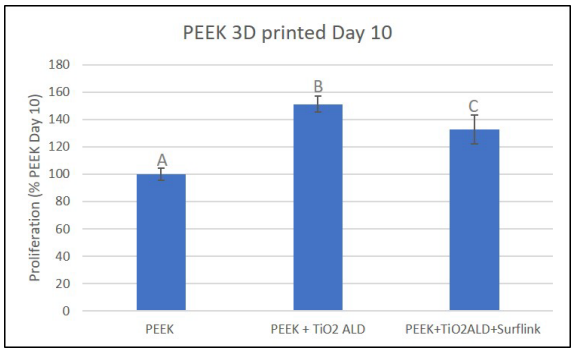

Fig. 1: Proliferation rate of osteoblasts 10 days after seeding on a bare 3D printed PEEK, coated with TiO_2-ALD and TiO_2-ALD-Surflink. Data expressed in % (100% is for bare PEEK) at day 10.

DISCUSSION & CONCLUSIONS: In our study, osteoblast (SaOS and HOS) proliferation on treated PEEK is significantly better for both treatments, TiO_2-ALD and TiO_2-ALD-Surflink vs. untreated PEEK. The results are slightly better for TiO_2-ALD as compared to TiO_2-ALD-SurfLink™. These are very first results and must be further confirmed, however it can be supposed that both treatments are fully suitable to enhance osteoblast proliferation on PEEK substrate. According to the studies carried out by NBM [1], SurfLink™ layer on titanium leads to an increase in early and mainly for long-term osseointegration as compared to untreated titanium.

Other tests according to ISO 10993 should be carried out to implement this surface treatment on industrially produced PEEK implants.

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[1]http://www.nbmolecules.com/documents/superior-surflink-characteristics.pdf

Comparative study of particle loads in peri-implant soft tissue over osteosynthesis plates made of CFR-PEEK and titanium

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INTRODUCTION: For locked plating of proximal humerus fractures, implants made of various materials are currently available. After titanium gradually replaced steel as the leading material in recent years, plates made of polymers such as carbon fiber reinforced polyetheretherketone (CRF-PEEK) became available. To the authors' knowledge, however, no publication has analysed the human tissue response to these novel materials for treatment of proximal humerus fractures.

METHODS: 16 patients (55.2±15.33 years; 62.5% female) with limited shoulder motion and/or persistent pain (n=8 titanium, Philos, DePuy Synthes; n=8 CFR-PEEK, PEEKPower humeral fracture plate, Arthrex) were examined. The peri-implant soft tissue, and plates were removed 13.7±5.8 months after fracture treatment. The soft tissue reaction and foreign bodies were identified and characterized using routine histology, immunohistochemistry, high-resolution computer tomography (CT), light, electron and infrared microscopy.

RESULTS: Histological sections from tissue adjacent to CFR-PEEK plates contained a large number of carbon fibers (Ø3 µm, Fig. 1) and round PEEK objects (Ø<5 µm).
Immunohistochemically, 6 samples were significantly positive for inflammation related markers (CD163, 25F9, CD68, MRP 8/14). In the tissue over titanium plates, a few scattered particles of titanium (Ø<3 µm) were identified, with slight CD68 reaction in 5 and low MRP8/14 reaction in 3 samples. PEEK and the carbon fibres were identified by infrared microscopy.
The surface of explanted CFR-PEEK plates showed exposed and broken carbon fibres (Fig. 2), whereas the titanium plates revealed scratches.

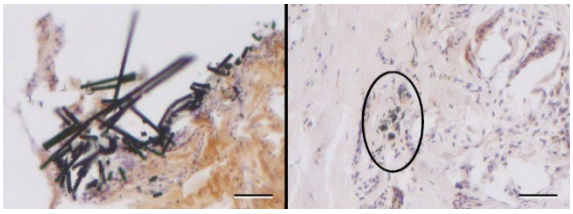

Fig. 1: Photos of histological sections of soft tissue next to CFR-PEEK plates (left) and titanium plates (right). On the left, large amounts of foreign bodies with rod-like and round configuration and significant tissue inflammation are evident. On the right, a few small foreign bodies (encircled) and less pronounced tissue inflammation are visible. Scale bars 50 µm.

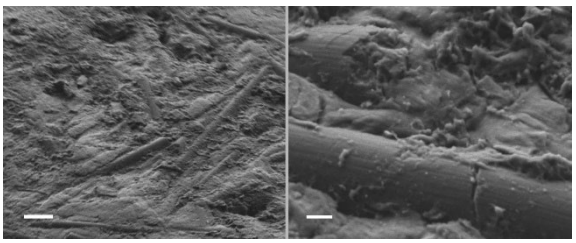

Fig. 2: At the surface of an explanted CFR-PEEK plate exposed and fractured carbon fibres are visible in scanning electron micrographs (scale bar left 10 µm, right 1 µm).

DISCUSSION & CONCLUSIONS: In the peri-implant tissue adjacent to CFR-PEEK plates, particles were observed in larger quantity compared to titanium plates. The inflammatory response was more distinct in the tissue adjacent to CFR-PEEK plates than to titanium plates. It could not be conclusively determined from which region of the implant the CFR-PEEK particles originated. However, looking at the implant characteristics, it is likely that they were released when the titanium screw heads were screwed into the holes of the CFR-PEEK plates.

In-silico implant validation: Establishing a reliable computational bone-implant model

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INTRODUCTION: The correct surgical fracture fixation can be challenging as the unique patient-specific biomechanical circumstances are usually neither considered in the design process of the implants nor their positioning. Finite Element (FE) analysis is a computational method which is increasingly being used for the preoperative planning and design improvement of osteosynthesis plates because it can uncover regions of high biomechanically induced stresses in the bone, implant or its interface which are difficult to measure experimentally [1]. Adopting this *in-silico* testing method in the clinics can ultimately improve the treatment outcome as it would give the surgeon an indication of whether the treatment is suitable for the patient without the need to experimentally test the mechanical integrity. The challenge lies within establishing the reliability of the simulation, i.e., the "digital twin" of the patient. The result of the *in-silico* simulation is especially useful when the computational model has been previously verified and validated experimentally. Among facial bones, the lower jaw is often affected by fractures, which in many cases require the fixation with an implant [2]. In this study, the principle of validation of an *in-silico* mandible fracture model is demonstrated.

METHODS & RESULTS: The digital mandible model was obtained by segmentation of patient computed tomography (CT) data. The mandible models were then produced with Selective Laser Sintering of Polyamide 12. For the FE model, material properties (e.g. Young's modulus, Poisson's ratio) of the bone model, implant and screw material were determined. Material properties of bone can be derived from the CT Hounsfield unit value of the patient's bone. The contact definitions and material properties were optimized by comparing the intact mandible FE outcomes to the deformation behaviour of the experimental model of a biomechanical setup. A frictional contact of $\mu = 0.1$ was chosen between the bone surface and the setup as well as between the implant and the bone. For biomechanical testing, a custom-made jig was used to apply a uniaxial load with a hydraulic testing machine to the mandibular angle region (Fig. 1). The stress-induced surface deformation was recorded with an optical scanning device capable of digital image correlation. Finally, the surface deformation and reaction force were statistically compared with the FE results and a high level of correlation was observed.

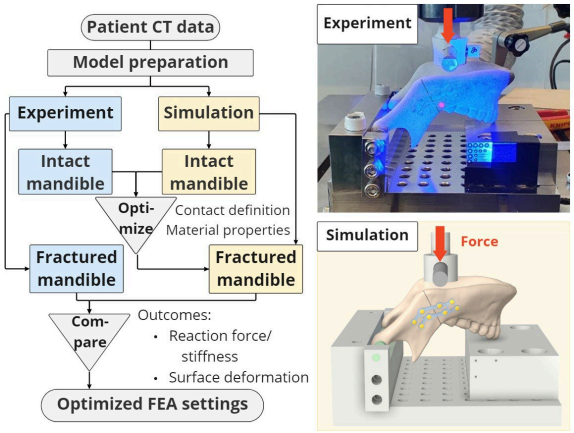

Figure 1 (left) Methodology of in-silico validation approach. (right) Depiction of the experimental setup and the CAD model for the FE analysis.

DISCUSSION: We proposed a workflow to virtually create a setup for mechanical bench testing of osteosynthesis plates on an additive-manufactured model of a patient's fractured jaw. We proved that the FE method can accurately depict mandibular fixation methods. With this method, patient anatomy and bone quality can be considered. The digital validation of implants can significantly speed up the process to bring effective osteosynthesis solutions to patients with time-critical traumatic injuries.

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Making an impact: In-vitro validation of operational strength of impact-loaded surgical instruments by means of an automated pendulum impact tester

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INTRODUCTION: Impact-loaded surgical instruments, e.g. hip cup positioners, are exposed to high forces at high loading rates. Validation of the operational strength of surgical instruments over their service life is becoming more important for product development and approval. The aim of this study was to establish a reproducible procedure to validate operational strength of such instruments.

METHODS: In a cadaveric study, the relevant forces and impulse time intervals were determined by a surgeon using an instrumented surgical hammer and a hip cup positioner. An identical hip cup positioner was tested in a specially constructed pendulum impact tester consisting of a striking element and pendulum arm with an adjustable deflection angle. Both the surgical hammer and the striking element were equipped with exactly the same piezo force transducer to determine the entry force over time.

Figure 1 shows the exemplary test setup: The entry force is shown by a red arrow (F_E) and the discharge force is illustrated by a blue arrow (F_D). The main parameters of the pendulum are defined by the length (l_P), mass (m_P) and angular deflection (α_P).

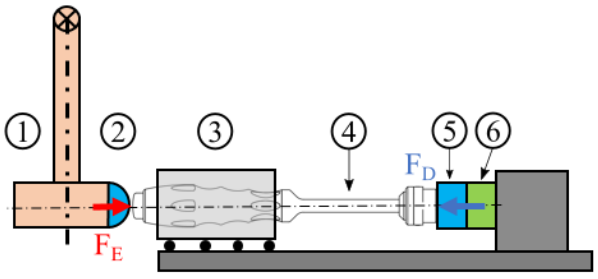

Figure 1: Exemplary setup of pendulum impact tester with pendulum (1), entry force transducer (2), instrument mounting fixture with linear bearing (3), surgical instrument (4), discharge force transducer (5), damping element (6).

RESULTS: The force amplitude of the surgeon's impacts varied during the hip cup impaction with an average force amplitude of 20.24 ± 7.35 kN. Therefore the deflection angle of the pendulum impact tester was adjusted to generate the average force amplitude of the surgeon.

Table 1: Comparison of impact signals from cadaveric study and pendulum impact tester regarding force amplitude and impulse interval duration.

Parameter	Cadaveric study (n=23)	Impact tester (n=36)
Average force amplitude [N]	20'240 ± 7'345	19'954 ± 345
Average impulse interval [µs]	260 ± 114	161 ± 15

DISCUSSION & CONCLUSIONS: The averaged intraoperative impact on the investigated hip cup positioner could be well reproduced by means of the pendulum impact tester. The authors believe that cyclic pendulum impact testing makes a valuable contribution to the validation of the operational strength of impact-loaded surgical instruments over their respective service life as well as contribute to the development and approval process of new instruments. This method may be applied to other kinds of insertion instruments of different geometry and averaged force amplitude.

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