Introduction: Implant devices for osteosyntheses are manufactured from stainless steel (316L) and commercially pure titanium (cpTi). Numerous experimental studies demonstrated superior biocompatibility for titanium, concluding a better capacity of bone healing and osseointegration as well as a reduced local inflammation. Stainless steel still is highly debatable due to whether it can exert adverse reactions due to its high nickel content. There aren’t any studies that confirm or contradict such conclusions, neither in a clinical study nor in an experimental setting which is designed according to conditions comparable to the clinical situation.

It is the aim of this study to comparatively investigate bone healing, wear of implant surfaces and local tissue reaction in plate osteosyntheses of stainless steel and titanium which are strictly comparable regarding individual, implant site, type of fracture and weight bearing.

Materials & Methods: Plate osteosyntheses with bicortical screw fixation (2.7mm) were performed after horizontal osteotomy of the right tibia in mature New Zealand White rabbits. Groups (316L and cpTi) consisted of 15 animals each. A standardized gap of 1mm within the osteotomy was left to achieve fretting at the plate/bone and at the screw/plate interface. To guarantee identical weight bearing of the osteosyntheses each animal was operated at a weight of 3.2kg and no restrictions for postoperative weight bearing under systemic analgesia (Temgesic®) were made. Groups were evaluated regarding local complications such as infection, impaired wound healing, fractures, implant loosening and non-union. Animals were sacrificed at day 56 when the expected consolidation of the tibiae was confirmed by x-ray control.

Tissue samples from the implant site were taken without further contamination (Keraknife®). Samples were fixed and embedded in methacrylate (Technovit®) for examination by light microscopy (Leica DC 100). For assessment of inflammation and wear particles, samples were stained with hematoxylin. To particularly identify macrophages and with Wilcoxon test for two independent samples. Differences were defined to be significant with a p-value < 0.05.

Results: Postoperative fractures of the operated tibia occurred in one animal of each group. There were no further complications i.e. no impaired wound healing or infections. All osteosyntheses were consolidated within the observation period.

Examination of the retrieved tissue samples revealed a more intense contamination from wear particles in cpTi-animals. Compared to 1.8 (0.6) particles/HPF in animals with osteosyntheses from stainless steel the local particle burden in cpTi-animals differed significantly at 14.1 (1.9) cells/HPF with a p-value being smaller 0.001. Concentration of titanium with an average of 3900.4 µg/g in tissue samples in cpTi-animals also showed an imposing difference to stainless steel with summarized 616.3 µg/g for Cr, Ni and Mn (p<0.001).

Histopathologic examination reflected the results described above. All animals with cpTi-implants had a severe inflammatory tissue response on wear particles which was dominated by macrophages. On average 18.8 (2.7) MAK-positive cells were detected in cpTi-animals meeting a grade 2 and grade 3 inflammation according to Mirra’s classification in 46% and 33% of animals respectively. In contrast, only 26% and 6% of animals with osteosyntheses from stainless steel showed a grade 2 or even a grade 3 inflammation with an average of 8.3 (1.5) cells/HPF in all 316L-animals. But also cells of chronic inflammation (monocytes, lymphocytes etc) were found in higher numbers in cpTi-animals with 21.7 cells/LPF (3.1) compared to 8.9 cells/LPF (1.3) in 316L-animals. All these differences were found to be significant with a p-value < 0.001.

Detection of the fracture repair tissue showed a comparable low apposition rate within the first three weeks in both groups with 4.1% in 316L-animals and 3.8% in cpTi. In 316L-animals labeling with alizarin-komplexon revealed a significant increase in bone formation within the fourth week up to 23.9% as well as a significant difference towards cpTi-animals with only 13.9% new formed bone within the former gap of the osteotomy. Although bone formation in cpTi-animals persisted on a higher level during the last period of the experiment compared to 316L (8.7% versus 2.9%) the overall bone formation rate differed significantly in favor of 316L-osteosyntheses with 30.7% versus 26.3% in cpTi-osteosyntheses.

Discussion: Internal fracture fixation by plate osteosynthesis is accompanied by corrosion, fretting and fatigue of implant devices. Despite previous studies which report on excellent biocompatibility of titanium which is considered to be superior to stainless steel, the presented study which represents a comparison of both implant materials in a weight bearing fracture like animal model, shows wear and foreign body reaction in both implant materials. Interestingly, signs of wear and corrosion were found to be even stronger in osteosyntheses from commercially pure titanium. Additionally, chronic and especially acute inflammation was found to be significantly increased in cpTitanium as well. Although the study is limited in terms of complexity regarding the fracture model the present study indicates, that giving comparable conditions in sense of type of fracture, mechanical load, individual conditions and implant design, commercially pure titanium cannot be assigned as the implant material of choice for osteosynthetic devices. The rate of new formed bone within the limitations of the animal model could support the above mentioned findings.

The results of this study seem to particulate contradict the common sense that titanium is generally superior to stainless steel and turn the scientific attention on direct comparison of these implant materials under comparable conditions which are clinically orientated.

DIFFERENT INFLAMMATORY TISSUE RESPONSE FOLLOWING PLATE OSTEOSYNTHESIS FROM TITANIUM AND STAINLESS STEEL IN RABBITS

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Poster No: 1622
53rd Annual Meeting of the Orthopaedic Research Society