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Biocompatibility features of silicon nitride ceramics and possible application for osteosynthesis systems.

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Objective: The favorable properties of silicon nitride (Si_3N_4) ceramics, e.g. superior resistance to wear, thermal shock, fracture toughness with nearly double mean strength level compared to aluminum oxide (Al_2O_3) suggest biomedical use as implant material for compression loaded conditions. The minor controversy about the biocompatibility of Si_3N_4 ceramics in the literature gave rise to the activities presented.
Materials and methods: Three consecutive steps of biocompatibility tests were performed: First, five qualities of Si_3N_4 ceramics of industrial standards were chosen for in vitro testing, applying an L929 - cell culture model in a direct contact assay. The chemical composition was determined by EDS analysis. Different Al_2O_3 qualities, a titanium alloy, glass and polyvinylchloride served as control materials. L929 mice fibroblasts were incubated directly on the materials. After 24 hrs they were stained with bisbenzimide and propidium iodine for double fluorochromasia viability testing and evaluated by inversion-fluorescence microscopy regarding cell morphology, viability and cell counts compared to empty well values. Scanning electron microscopy was applied for additional investigation of cell morphology. Second, three Cylinders of Si_3N_4 were implanted "press fit" into each of the right lateral condyli of the femurs of 6 New Zealand white male rabbits. The contralateral femurs were implanted with Al_2O_3 as a control. Microradiographs and histological sections were obtained after 4 and 8 weeks. Morphometric assessment of bone-implant attachment was performed using a digital image analysing system. Third, as a result of thorough biophysical investigation, Si_3N_4-miniplates and -screws were manufactured and implanted for osteosynthesis of the frontal bone of three minipigs. Intramuscular injections of fluorescent dyes were applied in one pig to investigate the chronology of bone healing. CT- and MRI-scans were performed, finally histological assessment was done according to procedures in the rabbits.
Results: In vitro, there was no observation of cytotoxic effects on the Si_3N_4-samples, cell morphology was the same as on Al_2O_3 and titanium. Viability testing revealed presence of avital cells exclusively on PVC. Cell counts showed significantly higher numbers on all polished materials. A comparison of cell counts, taking into account the distribution of elements in the different silicon nitride samples suggests that the ratio of silicon to nitrogen and the amount of oxygen content influences cell proliferation. In vivo (rabbits), percentages of bone-implant attachment ranged from 58 to 65%. There was no statistically different percentage of bone-implant attachment between Al_2O_3 and Si_3N_4 after 4 and 8 weeks. During the period of 4 to 8 weeks after implantation there was a significant decrease of bone-implant attachment for Al_2O_3 compared to Si_3N_4. Si_3N_4-miniplates and screws showed satisfying intraoperative workability, only one of 24 screws broke, when intentionally overscrewed. In the minipigs there was no implant-loss, -displacement or –fracture. Bone healing was complete in all animals. Formation of new bone was observed in direct contact to the implants. The implants did not interfere with CT and MRI- scanning.
Conclusions: Si_3N_4 ceramics show a good biocompatibility outcome both in vitro and in vivo. Our investigations suggest that Si_3N_4 presumably yields even better osseointegration than Al_2O_3, and should therefore be considered for biomedical application in humans. Possible indications for this biomaterial in ENT-surgery include reconstruction of the skull base, ossicular chain reconstruction and osteosynthesis of bone of the mid face. To our knowledge, this is the first introduction of a ceramic-based miniplate-osteosynthesis-system. Advantages compared to titanium are: No risk of implantation with mucosal attachment, no medical need for explantation, no interference with radiological imaging. Disadvantages include the lack of individual bending of the miniplates. The stability of Si_3N_4 ceramics would also be of use for compression loaded conditions in orthopædics.

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