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Abstract

Individualized, drug delivering implants for treatment of otologic and rhinologic disorders

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Specific oto- and rhinologic disorders such as recurrent outer ear canal infections, middle ear infections, tinnitus, and hearing loss or chronic rhinosinusitis as well as implant based pathologies such as peri-implant fibrosis or implantation related hearing loss can and should be treated by pharmacotherapy. Local pharmacotherapy to the inner ear and frontal sinus is very challenging due to physiological barriers like the blood-labyrinth barrier (BLB) or the close proximity of the frontal sinus to easily vulnerable structures like the orbital cavity and the skull base. Up to now, the results of otologic and rhinologic drug therapy are heterogeneous since the drug delivery devices are not exactly tailored to the patients needs. Individualized implants, exactly fitting to the patient's anatomy, will help to overcome this lack of therapeutic benefit. To allow an atraumatic implantation of individualized implants into the anatomical niches and sinuses, the implant needs to be mechanically flexible. We are developing a process chain from clinical images (cone beam computed tomography), semi-automated segmentation of the region of interest using a custom-made software, 3D-printing of drug-containing material to clinical application. Implants for the outer ear canal, round window niche and frontal sinus are printed containing dexamethasone. Implants are 3D printed by a 3D-Bioplotter® Manufacturers Series (EnvisionTEC GmbH, Gladbeck, Germany) using medical-grade silicone (60A MG, BIO-83-6001, EnvisionTEC, silicone elastomer curing at 365 nm, USP Class VI). The printed specimens are tested for drug release, biocompatibility and –efficacy in vitro and in vivo. The additive manufacturing method allows the development of implants in a large volume range. The precision is acceptable for the intended applications; drug is released out of the samples and causes biological effects in vitro. Biocompatibility is given and first individual healing attempts using this novel generation of implants are performed and suggest safety and compliance.

AUTHOR'S STATEMENT

Conflict of interest: D. Alcacer Labrador and S. John are employees of HörSys GmbH; F. Repp is an employee of OtoJig GmbH; T. Lenarz is shareholder of OtoJig GmbH and OtoJig GmbH. Informed consent: Informed consent has been obtained from all individuals included in this study. Ethical approval: The research related to human use complies with all the relevant national regulations, institutional policies and was performed in accordance with the tenets of the Helsinki Declaration, and has been approved by the authors' institutional review board. Acknowledgments: The authors would like to thank the Federal Ministry of Education and Research of Germany (BMBF) for funding the project 'RESPONSE – Partnership for Innovation in Implant Technology' in the program 'Zwanzig20 – Partnership for Innovation'.

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