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Abstract

Patient-individualized drug-delivering implants in otorhinolaryngology

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In various clinical fields, anatomical changes occur during the surgical procedure, for example in otorhinolaryngology when removing tumorous tissue from the middle ear or expurgating ossified structures in the treatment of chronic sinusitis. Pharmacotherapy enables or supports healing. However, treating these conditions or other anatomical structures in the skull such as the inner ear is challenging due to physiological barriers, such as the blood-labyrinth barrier (BLB). Systemic pharmacotherapy, oral or intravenous, requires very high doses in order to attain sufficient drug bioavailability in the before mentioned structures. This this comes with massive adverse events and/or the risk of failing to achieve a sufficient drug concentration in the target region, leading to inconsistent results of drug therapies in clinical settings. Local, sustained delivery of medications can solve these problems. However, prefabricated drug delivering implants often do not fit the novel anatomical situation created during surgery in the patient. Existing local drug delivery devices are not specifically designed to meet the unique needs and anatomical specificities of individual patients. The development of individualized implants that perfectly match a patient's anatomy is crucial. These customized implants allow the local delivery of active ingredients into physiological anatomical cavities and anatomical conditions newly created by surgical interventions. Importantly, the printed implants need to be mechanically flexible to ensure a gentle and precise implantation.

Additive technologies such as fused deposition modeling, material jetting, stereolithography or two-photon polymerization make it possible to adapt implants to a patient's individual anatomy while ensuring optimal loading with active substances. We established a comprehensive process chain that begins with 3D clinical images of the target structure. These images are processed using a custom-made software that enables semi-automated segmentation of the region of interest. The next step involves 3D-printing the implants using drug-loaded medical-grade USP Class VI silicone [1]. The additively manufactured implants are specifically designed for the outer ear canal, round window niche, and frontal sinus, and they contain repurposed drugs. Drug release, biocompatibility, bio-efficacy, accuracy, and precision are evaluated. Initial individual healing attempts using this novel generation of implants have been conducted, demonstrating promising safety and compliance as well as a beneficial effect for the patient.

AUTHOR'S STATEMENT

Conflict of interest: the authors declare no conflict of interest. Informed consent: Informed consent was 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.

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