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Abstract

Development of a biodegradable patient-individualized drug delivery round window niche implant (RNI) for inner ear therapy

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Inner ear disorders such as idiopathic sudden sensorineural hearing loss, tinnitus, or Morbus Menière are highly prevalent. The inner ear's physical limitations, its rate of metabolism, and the presence of the blood-labyrinth barrier [1], limit the accessibility and hinders therefore the efficacy of various pharmacological treatments of the inner ear. As a result, efficient drug delivery to the inner ear continues to be a major area of research and an unmet medical need [2]. Since the cochlea itself and the round window niche in particular have a large individual anatomical variability, one drug delivery system may not fit all patients, and there is a requirement for personalized drug delivery implants to optimize cochlear treatment. Additive manufacturing (3D printing) offers a solution to all these problems. 3D printing can allow the size, shape and internal structural features to be modified according to the patient's needs. Therefore, 3D printing enables the design of drug delivery implants adapted to the individual anatomical needs of the patient. The potential of 3D printing in personalized drug delivery systems could revolutionize the local drug delivery in and to the inner ear. We aim to combine drug-eluting, biodegradable, polycaprolactone-nanoparticles (PCL- NPs) with alginate hydrogel for 3D printing, with the goal of developing a novel, biodegradable individualized drug delivering round window niche implant (RNI) for inner ear therapy. The construct will consist of drug laden PCL-NPs, which are encapsulated in alginate that is 3D printed in the intended patients-individual shape. Our hypothesis is that the PCL-NPs will lead tostabilization of the alginate and sustained drug release properties. We use the double emulsion solvent evaporation technique to produce the PCL- NPs which are combined with alginate hydrogel to form a printable bioink. The effect of various combinations of the concentration of alginate, pre-crosslinker (CaCl2) and PCL-NPs on the printability are investigated. In addition, the influence of printing parameters such as extrusion speed and pressure were analyzed. Our results show that the combination of PCL- NPs and alginate allows for 3D printing. Alginate hydrogels above 6% concentration can be printed. Combining PCL-NPs and pre-crosslinking can significantly improve printing accuracy. We plan to further optimize the printing parameters, investigate physicochemical properties, drug release kinetics, biocompatibility and bio-efficacy.

AUTHOR'S STATEMENT

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