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*Abstract*

# Engineering of a polycaprolactone-stabilized alginate hydrogel for 3D bioprinting of patient-specific implants enabling sustained local dexamethasone delivery in inner ear therapy

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There is an unfulfilled need for local inner ear therapy to treat hearing disorders. We developed a silicone implant enabling drug diffusion from the middle ear into the inner ear. This implant is precisely tailored to conform to the unique anatomical contours of each patient's round window niche, thereby facilitating controlled diffusion of therapeutic agents into the inner ear. To improve the approach biodegradation of the implant would be beneficial to avoid the potential need of explanting the drug delivery device. Alginate hydrogels are well-established for their cytocompatibility and biodegradability. But they are inherently limited by insufficient viscosity and suboptimal mechanical integrity, restricting their applicability in 3D bioprinting. To overcome these deficiencies, we engineered a composite hydrogel system through the incorporation of polycaprolactone particles (PCL) to modify the printability. Dexamethasone was used as model drug. The composite material was 3D printable and compression tests and rheological tests determined the elastic properties and structural stability under certain loads. Investigations into swelling kinetics and morphological stability under simulated physiological conditions substantiated the material's durability and functional integrity within 7 days and subsequent degradation over time. By day 84, the cumulative release of DEX reached approximately 3% (5% DEX pre-load), and 12% (1% DEX pre-load). In vitro release kinetics of dexamethasone quantified through high-performance liquid chromatography (HPLC). Cytotoxicity tests demonstrated biocompatibility (> 80% survival rate), and the dexamethasone-loaded hydrogel elicited anti-inflammatory responses in vitro. The PCL-reinforced alginate hydrogel represents a promising platform for the development of personalized, biodegradable, and pharmacologically active implants. However, further preclinical characterization is essential before clinical translation can be pursued.

**AUTHOR'S STATEMENT**

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