

Bioresorbable Medicament-Eluting Grommet Tube for Otitis Media with Effusion

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Abstract : Otitis media with effusion (OME) is the leading cause of hearing loss in children worldwide. Surgery to insert grommet tube into the eardrum is usually indicated for OME unresponsive to antimicrobial therapy. It is the most common surgery for children. However, current commercially available grommet tubes are non-bioresorbable, not drug-treated, with unpredictable duration of retention on the eardrum to ventilate middle ear. Their functionality is impaired when clogged or chronically infected, requiring additional surgery to remove/reinsert grommet tubes. We envisaged that a novel fully bioresorbable grommet tube with sustained antibiotic release technology could address these drawbacks. In this study, drug-loaded bioresorbable poly(L-lactide-co- ϵ -caprolactone)(PLC) copolymer grommet tubes were fabricated by microinjection moulding technique. In vitro drug release and degradation model of PLC tubes were studied. Antibacterial property was evaluated by incubating PLC tubes with *P. aeruginosa* broth. Surface morphology was analyzed using scanning electron microscopy. A preliminary animal study was conducted using guinea pigs as an in vivo model to evaluate PLC tubes with and without drug, with commercial Mini Shah grommet tube as comparison. Our in vitro data showed sustained drug release over 3 months. All PLC tubes revealed exponential degradation profiles over time. Modeling predicted loss of tube functionality in water to be approximately 14 weeks and 17 weeks for PLC with and without drug, respectively. Generally, PLC tubes had less bacteria adherence, which were attributed to the much smoother tube surfaces compared to Mini Shah. Antibiotic from PLC tube further made bacteria adherence on surface negligible. They showed neither inflammation nor otorrhea after 18 weeks post-insertion in the eardrums of guinea pigs, but had demonstrated severe degree of bioresorption. Histology confirmed the new PLC tubes were biocompatible. Analyses on the PLC tubes in the eardrums showed bioresorption profiles close to our in vitro degradation models. The bioresorbable antibiotic-loaded grommet tubes showed good predictability in functionality. The smooth surface and sustained release technology reduced the risk of tube infection. Tube functional duration of 18 weeks allowed sufficient ventilation period to treat OME. Our ongoing studies include modifying the surface properties with protein coating, optimizing the drug dosage in the tubes to enhance their performances, evaluating their functional outcome on hearing after full resorption of grommet tube and healing of eardrums, and developing animal model with OME to further validate our in vitro models.

Keywords : bioresorbable polymer, drug release, grommet tube, guinea pigs, otitis media with effusion

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