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Abstract

Novel bilayer mucoadhesive patches for delivery of clobetasol-17-propionate to the oral mucosa to treat oral lichen planus; an *in vitro* and *in vivo* evaluation

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Objectives:

Oral lichen planus (OLP) and recurrent aphthous stomatitis (RAS) are chronic inflammatory conditions often characterised by erosive and/or painful oral lesions that have a considerable impact on quality of life. Current treatment often necessitates the use of steroids in the form of mouthwashes, creams or ointments but these are often ineffective due to inadequate drug contact times with the lesion. Here we evaluate the performance of novel bilayer mucoadhesive patches for uni-directional delivery of the steroid Clobetasol-17-propionate to the oral mucosa.

Methods:

Electrospun polymeric patches with an impermeable backing layer and mucoadhesive drug delivery layer were produced and characterised for their physical properties in the laboratory. The drug release profile, drug penetration and cytotoxicity of the system in delivering Clobetasol-17-proprionate was evaluated using *ex-vivo* porcine oral mucosa and tissue engineered human oral mucosa. The ability of the system to deliver Clobetasol -17-proprionate effectively into the oral mucosa, and local and systemic drug safety was then confirmed in *in vivo* mini-pig studies before evaluation of residence time and acceptability of the drug delivery system in a human volunteer study.

Results:

Clobetasol-17-propionate incorporated into the patches was released in a sustained manner in both tissue-engineered oral mucosa and *ex vivo* porcine mucosa. Clobetasol-17 propionate-loaded patches were further evaluated for residence time and drug release in an *in vivo* animal model and demonstrated prolonged adhesion and drug release at therapeutic-relevant doses and time points without local or systemic toxicity. Human studies confirmed long adhesion (residence) times and high levels of patient acceptability for use of the oral adhesive patches for treatment of oral mucosal disease.

Conclusions:

These data show that electrospun patches are adherent to mucosal tissue without causing tissue damage, and can successfully be loaded with and release Clobetasol and potentially other clinically active drugs into the oral mucosae in a sustained therapeutic manner. These patches hold great promise for improving the treatment of OLP, RAS and other immunoinflammatory oral diseases and are ready to enter phase 2 clinical trials.