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Version: Accepted Version

Proceedings Paper:

Hadley, L., Santocildes-Romero, M.E., Thornhill, M.H. et al. (2016) Pre-clinical evaluation of novel electrospun patches for intra-oral drug delivery. In: Oral Diseases. 13th Biennial Congress of the European Association of Oral Medicine, 15-17 Sep 2016, Torino, Italy. Wiley, pp. 10-13. ISSN: 1354-523X. EISSN: 1601-0825.

<https://doi.org/10.1111/odi.12558>

This is the peer reviewed version of the following article: Pre-clinical evaluation of novel electrospun patches for intra-oral drug delivery, Oral Diseases (2016) 22 (Suppl. 2), 10–13 doi:10.1111/odi.12558, which has been published in final form at <https://doi.org/10.1111/odi.12558>. This article may be used for non-commercial purposes in accordance with Wiley Terms and Conditions for Use of Self-Archived Versions.

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Pre-clinical evaluation of novel electrospun patches for intra-oral drug delivery

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Objective: Oral lichen planus (OLP) is a chronic inflammatory condition often characterised by painful or erosive oral lesions that have a considerable impact on a patient's quality of life. Current treatment often necessitates the use of steroids in the form of mouthwashes, creams or sprays but these can be ineffective due to low drug contact times with the lesion. The aim of this project was to evaluate the performance of novel uni-directional electrospun drug delivery oral patches as a possible therapeutic treatment for OLP.

Methods: The physical properties of patch formulations were tested using thickness, weight, microenvironment pH, elasticity and tensile strength measurements. **Ex vivo** porcine buccal mucosa was used to evaluate the muco-adhesive residence time, and the physical interactions between patch and porcine tissue were analysed using H&E-stained cryosections. Tissue-engineered oral mucosa was prepared to evaluate patch cytotoxicity using LDH and MTT assays, and steroid release and delivery through tissue-engineered epithelium was measured by HPLC.

Results: Oral patches were robust, showed reproducible thickness and weight measurements, and did not alter the microenvironment pH. Residence time tests showed that patches adhered to porcine tissue rapidly and remained in place for more than 5 h. Cryosections and viability assays showed the patches made intimate contacts with both porcine and tissue-engineered oral mucosa with negligible cytotoxicity. HPLC detected rapid drug release from patches that penetrated tissue-engineered mucosa.

Conclusion & Relevance: These data show that electrospun oral patches are highly adherent to mucosal tissue without causing tissue damage, and can be successfully loaded with and release clinically active drugs. They hold great promise for the treatment of oral conditions such as OLP and potentially other oral lesions.