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Adhesion and acceptability of novel oral patches in human volunteers

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Objective: Oral lesions such as Oral lichen planus (OLP) or Aphthous Ulcers are often characterised by painful or erosive oral lesions. These lesions are often treated with steroid-containing mouthwashes or creams but these preparations can be ineffective due to low drug contact times. We have created an oral adhesive patch using electrospinning technology that is able to firmly adhere to porcine and tissue-engineered oral mucosa for prolonged periods and so may be able to deliver drugs directly to a lesion. In this study we examine the adherence of drug-free oral patches in human volunteers to determine their longevity and acceptability in humans.

Methods: Oral patches were placed on the buccal mucosa, lateral tongue or gingiva of healthy human volunteers (with written, informed consent; n=36) for 5 seconds with applied pressure and residence time measured every 10 minutes for up to 2 hours. Volunteers were also asked to complete a questionnaire to provide information on patch performance, comfortableness and acceptability.

Results: Oral patches were highly adherent to the human oral mucosal tissues with 100%, 89% and 86% of patches remaining adherent to the gingiva, tongue or buccal mucosa, respectively for 2 hours. 94% of volunteers felt the patches provided good/excellent adherence and over 70% of volunteers felt no irritation whilst wearing the patches. The majority of volunteers (>70%) stated that the patches were comfortable to wear and although 16% reported moderate interference with speech over 70% stated only minor affects on saliva production and swallowing. 97% of volunteers stated that they would be willing to wear the patch twice-a-day to treat an oral lesion if required.

Conclusion: Electrospun oral patches were strongly adherent to different sites of the oral mucosal for prolonged periods and, overall, were well tolerated. These patches have great potential to deliver drugs directly to oral lesions.