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Conference Abstract

A strategy for assessing muco-adhesive potential in dosage forms employing bio-adhesive materials

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SUMMARY

Robust, repeatable bio-adhesive assessment method designs and assays are paramount for comparing various formulation compositions and their activity. Various methods of assessment exist but there is no consensus nor harmonisation of an approach to assessment. In this study we demonstrate detachment force assessment and experimental design in generating reproducible data that can demonstrate the trending similarities or differences between various mucoadhesive dosage forms that facilitate the characterisation, screening and grouping of bio-adhesive dosage forms based on their dynamic activity.

INTRODUCTION

The application of "bio-adhesive" materials in the formulation of various dosage forms have been previously reviewed (Lee et al. 2000, Smart 2005), highlighting the improvements to formulation performance with respect to localised treatment , drug bio-availability and controlled release properties. Numerous methods of bio-adhesive assessment exist that have been previously reviewed (Woertz et al. 2013). With a variety of methods, come a diversity in instrument set-up and experiment designs that influence the overall data that is produced, and presents an issue when trying to compare data across methods and experimental designs (Bassi et al. 2018). In this study we aim to describe and demonstrate an optimised acquisition method as well as experimental design capable of fast screening and comparative data analysis across a series of mucoadhesive formulations employing different bio-adhesive polymers.

MATERIALS AND METHODS

Glycerol, Oleic Acid, Porcine Mucin and Pluronic-F127 were purchased from Sigma Aldrich, UK. Kollisolv P124 Geismar was donated by BASF, Polyox WSR N60 LEO NF was donated by Colorcon, Honey purchased locally.

A series of formulations highlighted in the table 1 were generated. Aiming to assess detachment force, we employed the TA-XT Plus Texture Analyser developed by Stable Microsystems. For a biological model mimicking a biological surface we employed mucin sourced from porcine stomach. We generated a series of mucin discs following optimisation for mechanical strength dry and wetted. Data for our formulations' activity was generated against the mucin disc surface in an activated (hydrated) state. For the repeatable generation of data, we employed the same acquisition method conditions for all samples. Each assessment cycle employed six (6) data points and each sample formulation was tested in triplicate. A clinically registered formulation already at market was employed as a positive control.

Table 1. *Composition of formulations for assessment.*

S - 1	S - 2	S - 3	S - 4
Oleic Acid	Oleic Acid	Oleic Acid	Oleic Acid
Glycerol	Glycerol	-	-
Honey	Honey	Honey	Honey
Water	Water	Water	Water
P - 124	P - 124	F - 127	F - 127
-	N60	-	N60

RESULTS AND DISCUSSION

Fig. 1. *Figure comparing detachment force results for S-4 (3) replicates.*

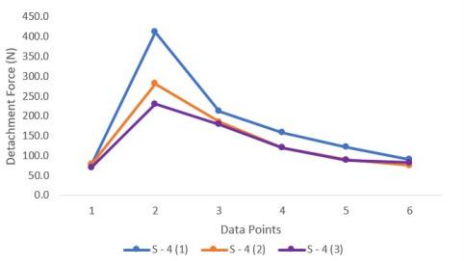


Fig. 2. *Figure comparing the mean detachment force results for all four formulations.*

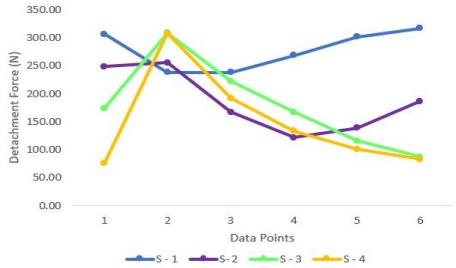
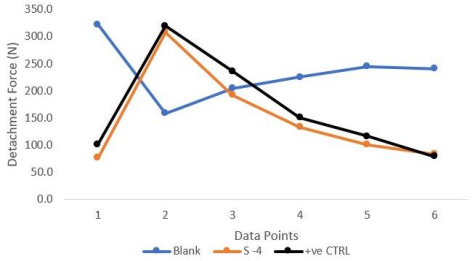


Fig. 3. *Figure comparing mean detachment force results for S-4 vs blank system vs +ve control.*



The results display a repeatable trend in formulation behaviour over six (6) acquisition points. For each replicate the same general trend is observed within a range of activity (fig.1). Clear differences as well as similarities in performance can be easily discerned amongst the different formulations assessed (fig.2). Similar trends in activity were observed in the positive control employed. S-4 displayed the most similar trend in activity to the positive control (fig.3). This data suggests that S-4 will display similar mucoadhesive potential and may be employed in similar applications as the +ve control. This method design describes detachment force against repeating instances of contact, that display a profile of behaviour against activity. Other study designs that focus on an average of instances (Amorós-Galicia et al 2022) in contrast to an accumulation of instances over time, do not describe the response profile to performance in a dynamic environment that can experience cycles of change.

CONCLUSIONS

Force of detachment assessment employing a texture analyser can be used as a robust method for screening, grouping or characterising formulations based on their adhesive capacities and our proposed approach to experiment design and data capture better describes dynamic performance over time.

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