Human mouthfeel panel investigating the acceptability of electrospun and solvent cast orodispersible films

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Abstract

A human panel study was performed to investigate the acceptability of orodispersible electrospun and solvent cast films. 50 healthy volunteers took two drug-free samples of polyvinyl alcohol films prepared by the two methods. On a 5-point hedonic scale, the volunteers assessed the films' perceived size, stickiness, thickness, disintegration time, thickening effect on saliva, and handling. The films manufactured by both methods were similar in their end-user acceptability. The modal values of perceived size, thickness, disintegration time, saliva thickening effect, and handling were high (4 or 5). However, for both, the stickiness mode was 2 (strongly sticky) and the only negative attribute. Both films were reported to take approximately 30 s to disintegrate completely in the mouth. Electrospun

films scored similarly high to solvent cast orodispersible films in most attributes of end-user acceptability. Electrospun films were marginally preferred, with 27 out of 50 participants picking electrospinning when presented with a forced choice test of both fabrication methods. This is the first study to show that electrospinning enables the fabrication of orodispersible films that are acceptable to adult human participants in terms of handling and mouthfeel and suggests that the potential for clinical translation of such formulations is high.

1. Introduction

Poor patient acceptability leads to low compliance with a dosage regimen. This can have a negative impact on treatment completion and clinical outcomes. Geriatric and paediatric patient populations have the most compliance issues owing to a lack of formulations matching their needs (Liu et al., 2014). The challenges that face those groups include issues with swallowing a solid dosage form, palatability problems, and error associated with intervention of a care-giver when administering a measured liquid dose (Borges et al., 2015; Vuddanda et al., 2016). Age-appropriate dosage forms offer a solution to these challenges (Lopez et al., 2015). Perhaps most importantly, these dosage forms should be palatable for the patient, with palatability being defined as the overall appreciation of a medicine's properties, such as its appearance, smell, taste, mouthfeel and aftertaste (Walsh et al., 2014).

Orodispersible films (ODF) are excellent candidates for age-appropriate formulations. They are thin, easy to swallow, can be formulated to be taste-masked and do not require water to be taken (Hanning et al., 2016). They also offer flexible dosing, possess no risk of choking and offer improved dose accuracy in comparison to syrups, which renders them suitable for paediatric drug delivery (Bala et al., 2013). Oral films are suitable to be given to children, but key attributes such as stickiness, disintegration time and thickness need to be optimised to ensure maximum acceptability (Scarpa et al., 2017). One limitation of ODFs is the potential for low drug loading however, with a maximum of approximately 50 mg per film (Visser et al., 2020).

The most common route to ODF preparation is solvent casting, in which a polymer and drug are dissolved in a solvent, charged into a die, and then the solvent evaporated. There has been a limited amount of previous research comparing polymers and their molecular weights in terms of their effects on the acceptability attributes of solvent cast films. Scarpa et al. found that the chemical structure and molecular weight of a polymer influence stickiness perception, and the molecular weight has a major influence on disintegration time (Scarpa et al., 2018). They concluded that 39 kDa polyvinyl alcohol (PVA) shows acceptable mouthfeel properties, hence this grade was selected for use in this study.

Solvent casting has limitations, however. The number of polymers and solvents which can be used are limited. The process may sometimes require heat, and thus may be unsuitable for thermolabile excipients and active ingredients (Lade Milind et al., 2013). It also often requires the addition of excipients such as plasticizers to improve the formulation properties, for example to lower the glass transition temperature and thus improve the mechanical properties of the films. This can be especially undesirable for a dosage form intended to be used in the paediatric population (Garsuch and Breitkreutz, 2010). Paediatric dosage forms should include the minimum amount of excipients possible, as detailed in the European Medicines Agency (EMA) guidance document (EMEA, 2013). This is the case even for excipients which are generally recognized as safe (GRAS) in adults, because there is limited safety data on the effect of exposure to excipients on children's developing organ systems.

Oral films can be produced by manufacturing methods other than solvent casting, such as by hot melt extrusion, rolling and electrospinning (Bala et al., 2013). The mechanical properties and plasticity of polymer films are influenced by the fabrication methods (Ghosal et al., 2018), and thus may also have an effect on mouthfeel acceptability. For instance, studies by Ghosal et al. (2018) showed that PVA films produced by solvent casting were brittle unless a high amount of glycerol was added, whereas electrospun films were more naturally flexible.

Electrospinning involves the preparation of a polymer solution in a volatile solvent (typically with a functional component present too), and the subsequent extrusion of this solution through a metal

needle towards a metal collector plate. A high (kV) potential difference is applied between the two, which results in the formation of non-woven fibre mats on the collector. The latter have traditionally been used for wound healing (Grip et al., 2018) or as biomedical scaffolds (Meinel et al., 2012), but have also been explored for oral drug delivery (Abdelhakim et al., 2019; Balogh et al., 2018, 2017; Celebioglu and Uyar, 2019; Domokos et al., 2019; Nitanan et al., 2013; Payab et al., 2014; Wu et al., 2015). Electrospinning as a fabrication technique has some inherent advantages; for instance, the non-woven mats produced have hugely increased surface area to volume ratios compared to traditional films, which can lead to faster dissolution (Williams et al., 2018). Electrospun formulations have been investigated for taste-masking (Samprasit et al., 2017, 2015), giving them potential for the production of age-appropriate formulations. Electrospinning also requires little to no addition of excipients, unlike solvent casting. Further, it does not require heat (in contrast to hot melt extrusion) therefore making it more suitable for application with a wider range of materials, particularly thermally labile drugs (Qi and Craig, 2015; Sergio Torres-Giner, Rocio Perez-Masia, 2016; Williams et al., 2012). The process can be scaled up to industrial production levels, with multiple companies now offering high throughput and GMP manufacture of electrospun products (Vass et al., 2019). However, while these advantages suggest that electrospinning may be a viable alternative in the preparation of ODFs, the question remains as to how patients will perceive films prepared in this manner. This is of fundamental importance for further development, as poor acceptability will undermine any performance advantages incurred by the nanofabrication approach.

In this study, the effect of the manufacturing method used to prepare ODFs on mouthfeel acceptability was explored. To do so, a human taste panel, the gold standard approach for assessing the palatability of a dosage form (Eckert et al., 2013; Soto et al., 2018), was designed and undertaken. Its aim was to assess the ability and willingness of healthy volunteers to self-administer placebo electrospun and solvent cast film formulations.

2. Methodology

2.1. Ethics

This study was a single centre, single blinded cross-over study and was conducted at the UCL School of Pharmacy. The study design was approved by the UCL Research Ethics Committee (REC; project ID: 15975/001). All data were handled in line with the General Data Protection Regulation 2018.

2.2. Participant recruitment

An email was sent out to UCL School of Pharmacy staff and students to recruit them to the study. We sought healthy volunteers between 18 and 60 years of age. Smokers and individuals who had received dental care up to 15 days before the panel or were taking any medical treatment known to affect saliva production, were excluded. Participants that had any allergies or known hypersensitivities to PVA were also excluded.

2.3. Formulation preparation and characterisation

PVA (Parteck® SRP 80 EMPROVE® ESSENTIAL Ph Eur, USP, JPE) oral films were purchased from Bioinicia (Valencia, Spain). These were manufactured in an ISO 7 clean room according to cGMP standards (FDA, 2004). The Bioinicia plant has GMP certification issued by the Agencia Española de Medicamento, the Spanish agency that issues the permits required for the manufacturing of pharmaceutical products whose authorisations are worldwide harmonised and recognised. The plant also has ISO13485 accreditation to manufacture biomedical devices based on the electrospinning technology, and ISO9001 to manufacture any items based on this technology.

A solution of 20 % w/v PVA in a mixture of deionized water and 2-propanol in a ratio 60:40 was used. The PVA was slowly added to the solvent mixture and then stirred at 450 RPM overnight at 50 °C. All the films were packaged in a clean environment. The films were packaged as follows: the primary packaging was an ultrapure silicon-free resin resealable bag, and the secondary packaging a pharmaceutical grade aluminised high oxygen barrier bag with zip closing mechanism, made of glossy

aluminium. The packaging was labelled with batch number, expiry date, REC approval ID, and a unique sample code.

2.3.1. Electrospinning

Electrospinning was performed using a Fluidnatek® LE-500 with a multi-needle spinneret (26 needles). The optimised parameters were 25 kV applied voltage, a flow rate of 15 mL/h (0.577 mL/h per needle) and a spinneret to collector distance of 15 cm. The temperature ranged between 20-21 ^{o}C and the relative humidity was 29 %. 25 gauge needles were used, and fibres collected on a rotating drum (100 RPM) and the sweep speed was 30 mm/s. All the films were packaged in a clean environment. The packaging was labelled with batch number, expiry date, REC approval ID, and a unique sample code.

2.3.2. Solvent casting

The PVA solution was poured over a sterilised stainless steel plate with dimensions 25 x 15 cm and allowed to dry in a controlled temperature and humidity chamber.

2.3.3. Characterisation

Film thicknesses were measured using a digital micrometer (S00014, Mitutoyo, Corp., Kawasaki, Japan) with ± 0.001 mm accuracy. Measurements were performed in triplicate with no force applied. The morphology of the materials was determined with a field emission scanning electron microscope (FE-SEM, S-4800, Hitachi High Technologies Corp., Tokyo, Japan). Analysis of fibre diameter was carried out with ImageJ (National Institutes of Health, Bethesda, MD, USA). Prior to imaging, samples were sputtered for 2 minutes with gold/palladium. For the electrospun samples, at least 60 fibres from three different SEM images were randomly selected and measured to quantify fibre size.

2.4. The panel

Participants were individually seated in front of a computer monitor displaying a questionnaire designed using the Qualtrics software (SAP America Inc., Seattle, Washington, USA), which was used to record their answers. The two drug-free PVA films were presented to each participant in a random order with a 5 min break between them, to allow for palate cleansing. The participants were offered

a plain cracker and water in this break, if they wished. Participants were not asked to cleanse their palates at the start of the experiment, nor were they discouraged from drinking water to aid in swallowing the films. A digital stopwatch was provided to allow participants to record disintegration time.

2.5. Data collection

A five-point hedonic scale, as used in other taste panels (Smith et al., 2013), was used to capture the acceptability of different attributes of the oral films (Figure 1).

The six attributes investigated were the acceptability of the films' perceived size, stickiness, thickness, disintegration time, saliva thickening effect, and handling. Questions evaluating the disintegration time, whether the full film was swallowed or not, and the overall acceptability of the formulation were additionally included. For disintegration time, participants were instructed to start the stopwatch as soon as the film was placed on their tongue, then stop it and record the time in seconds when they felt it has disintegrated completely. The same questionnaire was completed by each participant for both samples. At the end of the survey the participants were asked to include any other open comments, and to choose a preferred film from the two tested.

2.6. Data analysis

Ordinal data were converted to discrete numerical values as detailed in Table 1. Data were then analysed using OriginPro 2017 (Origin Lab, Wellesley Hills, MA, USA).

Table 1. Conversion of ordinal quality attribute ratings into discrete numerical values.

Value	Quality attribute	Stickiness	Saliva thickening	Overall acceptability
1	Extremely uncomfortable	Extremely sticky	Extremely thickened	Extremely bad
2	Somewhat uncomfortable	Strongly sticky	Strongly thickened	Somewhat bad
3	Neither comfortable nor uncomfortable	Moderately sticky	Moderately thickened	Neither good nor bad

4	Somewhat comfortable	Slightly sticky	Slightly thickened	Somewhat good
5	Extremely comfortable	Not sticky	Not thickened	Extremely good

The numerical data from the acceptability attributes were then presented in a box plot, showing the median response and interquartile range (IQR). Significance tests were used to assess the magnitude of statistical associations. The data were non-parametric, and therefore a Paired Sample Wilcoxon Signed Ranks Test was used. The significance level was set at P = 0.05. A Fisher's Exact Test was used to assess whether the overall preference difference between the two films was statistically significant.

Modal data were used to compare the attributes between both films. The mode here is the rating that occurs most frequently and is also regarded as the best way to measure the central tendency for data measured on a nominal scale (Manikandan, 2011).

3. Results and discussion

3.1. Film characterisation

The electrospun films had a mass in the range of 22-26 mg, with a mean mass of 24.94 ± 1.04 mg. They were cut to 3 x 2 cm, with a thickness of 253 ± 10 µm (Figure 2). The cast films were generated with an equivalent mass or 25.35 ± 1.40 mg, resulting in dimensions of 2 x 1.7 cm and a thickness of 83 ± 10 µm (Figure 2). It is clear that the two formulations have different sizes and colours, which could impact acceptability attributes such as handling.

The films were imaged using SEM, with images shown in Figure 3.

3.2. Sample acceptability

50 participants (14 male and 36 female) were recruited for the study. The median age was 22 (min: 18; max: 49). Each participant received one sample of an electrospun film and one of a solvent cast film. The order the films were presented in was alternated between participants. No adverse effects associated with sample intake were reported by any participants during or after the study.

The hedonic-scale question in the survey assessed a number of characteristics that could affect the overall mouthfeel acceptability of the films. Box plots showing how the participants scored the films are given in Figure 4. Stickiness was the only attribute that had a median score of 3 for the solvent-cast films. The median score for the remaining five of the six attributes was 4, denoting a somewhat comfortable formulation. This is consistent with the literature, reaffirming that solvent cast oral films are acceptable for use by end-users (Scarpa et al., 2017). Outliers were observed in the data collected for the saliva thickening effect and handling of the solvent cast films, yet these were only noted with 2 or 3 out of 50 measures.

The decision was taken to match the ODFs by mass rather than size, because research by Scarpa et al. (2018) showed that the polymer mass represents the most reliable way to compare formulations. It was not possible to match both size and mass in the same experiment, but controlling for size instead is an important avenue that will be explored in future work. For the electrospun formulation, perceptions of size and thickness in the mouth scored particularly highly, with 88 % of the participants choosing 5 (extremely comfortable) or 4 (somewhat comfortable). Similar to solvent cast films, both those attributes had a median score of 4 overall. There was one outlier score of 2, or a somewhat uncomfortable formulation, for both size and thickness. It seems therefore that the participants preferred larger and thicker films, which may be explained by the fact that they are easier to administer into the mouth, not necessarily because they were electrospun or solvent cast.

Participant assessments of disintegration time and saliva thickening effect were similar, with a median score of 4 but a slightly larger range. Handling of the sample also had a median score of 4, but the range of responses extended to 1 (an extremely uncomfortable formulation). Stickiness scores were lower, with a median of 3 (neither comfortable nor uncomfortable), which is the same as the electrospun films, denoting that stickiness may be the largest barrier for films' acceptability from the attributes tested (Scarpa et al., 2017).

At first glance, the acceptability attributes scoring of both sets of films are very similar. The median values are the same for thickness, disintegration time, saliva thickening effect, stickiness and handling of the films.

Differences between the formulations can be seen when considering the modal values (Table 2). Because the rankings cover a small range of only 5 choices, a modal value can present a more reliable way of comparing acceptability since there are a lot of repeated values in this dataset. Table 2 also shows the quality attributes scoring the most 5s or extremely comfortable for both films.

Table 2. Modal ratings of quality attributes for the PVA ODFs manufactured by both methods. % demonstrates attributes scoring the most 5s or extremely comfortable.

Quality attribute	Electrospinning		Solvent casting	
	Modal value	Score = 5 (%)	Modal value	Score = 5 (%)
Thickness	5	48	4	26
Size	4	42	4	34
Disintegration time	5	38	4	30
Handling	4	34	5	46
Saliva thickening effect	4	26	4	18
Stickiness	2	16	2	10

The percentage of participants ranking any of the attributes as extremely comfortable (5) was higher for every quality attribute when comparing electrospun to solvent cast films, apart from handling of the films (34 vs 46 %).There was a positive difference of 8% for scores of extremely comfortable for the perceived film size in the mouth, saliva thickening effect, and disintegration time of the electrospun film. The differences between fabrication methods in the acceptability of size and thickening effect on saliva were statistically significant, with P-values of 0.03096 and 0.0012, respectively. However, as previously mentioned, the sizes of the films were different, and therefore it

is believed the participants may have preferred the larger films for the ease of administration, and not necessarily because they were electrospun. Disintegration time differences were not found to be statistically significant (P = 0.35).

The samples were controlled for mass, and because the electrospun films are less dense they had a larger size of 3 cm x 2 cm (thickness approximately 250 μm), whereas the solvent cast films were 2 cm x 1.7 cm in size (thickness approximately 85 μm). It was not possible to make the solvent cast films larger in size and keep their mass comparable to fibres, because this would have resulted in them being too thin to handle. The acceptability results for size and thickness of the films therefore do not necessarily represent superiority of either method, but relate to the general acceptability of size/ thickness of films.

The thickness and handling of the samples show the clearest differences between the electrospun and solvent cast films. The different densities of the films can impact the thickness perception, with 22 % more participants selecting extremely comfortable for the thickness of the electrospun film. This difference was, however, not statistically significant, with P = 0.66. The thickness of the electrospun films was the most highly rated attribute, whereas for solvent cast films this was the 4th attribute in rating order. It can be concluded that participants prefer thicker films therefore, irrespective of fabrication method. In contrast, handling was the highest rated acceptability attribute for the cast film. The ease of handling of the films was the only attribute where participants ranked the solvent cast system more highly, but this was not statistically significant (P = 0.09). With regards to stickiness, a positive difference of 6 % was observed for electrospun films, but this again was not a statistically significant finding (P = 0.53). This is to be expected, given that stickiness is a factor mostly dependent on the film composition (polymer), which is identical for both formulations.

3.3. Stickiness intensity

It is recognised that stickiness of oral films can be undesirable (Scarpa et al., 2018). It was hypothesised that as the stickiness intensity increases so will the undesirability of the formulation. In Section 3.2., it is shown that stickiness scored lowest amongst the acceptability attributes, with a median of 3 and mode of 2 for both manufacturing methods. Figure 5 is a bar chart depicting the stickiness intensity. This refers to the perception the user experiences when placing the film in their mouth, rather than comfort or discomfort associated with that feeling (as measured in Section 3.2.). For example, an individual may find a film sticky yet comfortable, or vice versa.

It can be seen in Figure 5 that the modal score for the electrospun films is 4, or only slightly sticky, and for solvent cast films the mode is 3, or moderately sticky. Actual discomfort associated with stickiness scored lower (Table 2) with modal value of 2 for both manufacturing methods. This suggests that the threshold for discomfort associated with stickiness intensity is quite low, and some work is needed to overcome this hurdle. In addition, this finding disproves the earlier hypothesis that both reported outcomes are correlated.

For both films, an equal percentage of participants picked 5, which equates to the samples not being perceived as sticky. More participants ranked the electrospun films as 4 (only slightly sticky), indicating a slight increase in acceptability over the cast films where more participants gave a score of 3 (moderately sticky). However, the difference observed between the films in terms of stickiness intensity was not statistically significant ($P = 0.07$), confirming the null hypothesis that both methods exhibit the same perceived stickiness.

3.4. Saliva thickening intensity

The thickening effect on saliva after placing the formulations on the tongue was the second least acceptable attribute for both manufacturing methods in terms of the number of participants selecting 5 or extremely comfortable. Similar to stickiness perception, a further question investigating the thickening effect intensity was asked. The saliva thickening effect feeling, or perception was explored,

rather than its subsequent comfort or discomfort (Figure 6). Again, it was hypothesised that the lower the thickening effect intensity was perceived to be, the more comfortable the mouthfeel. It can be seen from the bar chart that both methods had a modal value of 4 or only slightly thickened saliva. This agrees with the hypothesis that intensity of the saliva thickening perceived is correlated to the level of comfort or discomfort reported, as the modal value of this (Table 2) is also 4.

The data in Figure 6 indicate that participants preferred electrospun to solvent cast films in terms of saliva thickening intensity. The saliva thickening effect, and therefore intensity, is important because it might indicate further unfavourable outcomes such as mouth dryness and difficulty swallowing (Villa et al., 2015), which would be likely to reduce patient compliance. The difference observed between both methods was statistically significant ($P = 7.21 \times 10^{-4}$). This concurs with the difference between comfort levels relating to saliva thickening effect, which was also found to be statistically significant.

3.5. Film swallowing and Disintegration time

Complete film swallowing data were captured in the final portion of the survey. One participant spat out the whole electrospun film, stopping the timer at 12 seconds, and four others spat it out with partial loss only after having the film in their mouth between 27 and 60 seconds. This did not raise any safety concerns from the participants. The questionnaire did not allow for capturing the causes of film loss and so it is not clear why this happened. However, it can be assumed it is not taste related since both films had the same composition. This is the first study investigating acceptability of electrospun films in human participants, which means there are no baseline data. Nonetheless, it is known that 35 % of the general population have difficulty in swallowing oral solid dosage forms (Patil and Shrivastava, 2014). Although most participants preferred the larger size of the electrospun sample, this also could be a reason why the film was spat, with the larger size leading to difficulty in swallowing. However, the particular reasons for this will need to be explored further, and perhaps more researcher observed outcomes should be incorporated in future studies. None of the solvent cast films were spat out.

35 participants indicated that the electrospun films disintegrated in under 1 minute, whilst the remaining ten reported times between 1 and 3 minutes. 40 participants found that the solvent cast films disintegrated in under a minute, with the remaining ten recording a time between 1 and 3 minutes. The electrospun films had a median disintegration time of 30 seconds, with a minimum value of 8 s and maximum of 120 s. The solvent cast films gave a median time of 34.5 s, with a minimum of 9 s and maximum of 136 s. Overall the solvent cast films took slightly longer to dissolve, but this difference was not statistically significant (P = 0.83).

3.6. Overall acceptability

There is a comprehensive definition of a preparation's acceptability in the EMA's guidance on pharmaceutical development of medicines for paediatric use (EMEA, 2013). It is stated that acceptability is determined by the characteristics of the product, such as palatability and swallowability. In this study, participants were asked to give their assessment of the acceptability of various attributes the authors deemed as key for an ODF's mouthfeel. At the end of the questionnaire, participants were asked to assess the overall acceptability of both films (Figure 7) by rating the formulations from extremely bad (1) to extremely good (5). The electrospun films scored slightly higher than solvent cast films for the extremely good rating, but this difference was not statistically significant (P = 0.54).

To further understand participants' overall preference, they were asked to choose a preferred formulation using a forced choice test of both formulations. Table 3 details the results.

Table 3. Overall participant preference of the ODFs produced by both methods.

Participants (number)	Electrospun films (%)	Solvent cast films (%)
Total (50)	54	46
Male (14)	64	36
Female (36)	50	50

A difference of 28 % was observed for the male participants in their ranking of electrospun films as more preferable, while female participants had no overall preference with an equal split for both formulations. The reasons for these differences are not clear, and need further investigation (Ruiz et al., 2019). It should also be noted that the male sample size was approximately 50 % of the number of female participants and therefore the data here have low power. There was no statistically significant difference in preference between males and females, with a P value of 0.37. Overall, 27 out of the 50 participants chose electrospun films as their preferred ODF over solvent cast films in a forced choice test, however, this difference is marginal and was not found to be statistically significant (P = 0.55).

Electrospun mats have been very widely explored as fast dissolving film formulations, with a Web of Science search conducted on 17 January 2020 yielding 95 hits for “electrospinning” AND “fast dissolving”. It has been very well established that the amorphous physical form of the drug in electrospun fibres, coupled with their very high surface area to volume ratio, can lead to enhanced solubility and dissolution rate (Göke et al., 2018; Irem and Uyar, 2019; Qin et al., 2019; Rustemkyzy et al., 2015; Sipos and Kazsoki, 2019; Song et al., 2019; Thakkar et al., 2019; Tort et al., 2019). However, to date the patient acceptability of electrospun formulations has not been explored. This is a crucial facet of their onward development into medicines and is addressed for the first time in this work. We show here that electrospun formulations are at least as acceptable to adults as solvent cast films and appear to be more acceptable in some aspects. This is an important finding: it is widely recognised that solvent cast films are acceptable to end-users (Raju et al., 2013; Scarpa et al., 2018; Speer et al., 2018; Tian et al., 2019), and from the data presented in this work it is clear that electrospun formulations will also be acceptable. Electrospun films hence comprise viable alternatives to solvent cast films. Given that scale up to industrial throughput is now possible (Vass et al., 2019) and clinical trials of electrospun formulations underway, (Rivelin, 2019) these results pave the way for the clinical translation of electrospun fibre formulations.

4. Conclusion

We report in this work the first study investigating the acceptability of electrospun orodispersible films. Placebo PVA films were prepared by solvent casting and electrospinning under GMP conditions and controlled to have equivalent mass but the latter was slightly bigger (3 x 2 cm vs 2 x 1.7 cm). A human panel comprising 50 healthy volunteers were asked to consider the thickness, size, disintegration time, handling, saliva thickening effect and stickiness of the formulations. The electrospun fibres in general performed at least on par with the solvent cast films. The modal values of perceived size, thickness, disintegration time saliva thickening effect, and handling were high (4 or 5) on the five-point hedonic scale. While the stickiness mode was 2 (strongly sticky) this was the only negative attribute. Both formulations were reported to disintegrate in approximately 30 s. These findings demonstrate for the first time that electrospun films scored similarly high to solvent cast ODFs in most sensory attributes of end-user acceptability, which renders them suitable for clinical translation.

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