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Theoretical considerations of the influence of polymer film coatings on the mechanical strength of tablets

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A theoretical analysis of the influence of polymer film coatings on the mechanical strength of tablets has been undertaken. Making some basic assumptions, the theory predicts that neither the thickness of the substrate nor that of the coating has any influence on which fractures first, this being solely determined by the ratio of the tensile fracture strength to the Young's modulus for the two materials. Such a finding suggests that in practice for film-coated tablets the substrate will usually fracture before the coating. Simple measurements of maximum failure loads are of little value in assessing the influence of film coating on the mechanical strength of tablets.

Polymer film coatings are often applied to increase the overall strength and resistance to attrition of tablets so as to minimize possible damage as a result of mechanical handling during high speed packing. Recent work (Fell et al 1979) on the mechanical strength of film-coated tablets has highlighted the need to characterize such a system at a more fundamental level than that suggested by Stern (1976). We now present a theoretical analysis of the influence of polymer film coatings on the mechanical strength of tablets, and discuss the implications of the analysis in the interpretation of experimental results and the design of test procedures.

Theory

Consider a right circular cylinder, diameter d, and thickness t_s, uniformly coated with a polymer film of thickness t_c, subjected to diametrically opposed point loads P, as shown in Fig. 1. It is first necessary to establish how the total load P is distributed (or shared) between the coatings and the substrate, i.e. to determine P_c and P_s, the portions of the load P carried by each layer of the coating and the substrate respectively. This depends on their relative stiffnesses and on the fact that, if the bond between the coating and substrate remains sound, the strains at all corresponding points in the coating and substrate will be identical.

† Correspondence.

The horizontal and vertical stresses (σ_1 and σ_2) at a general point on the vertical diameter of the loaded

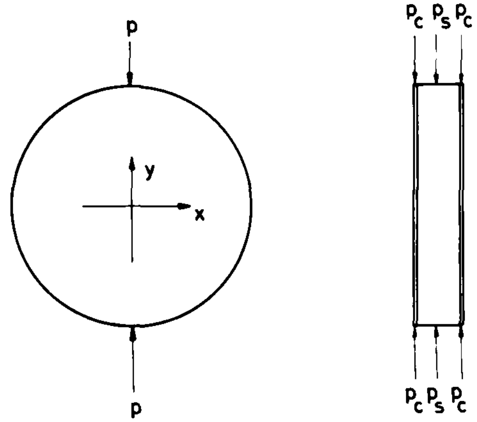

FIG. 1. Coated tablet subjected to diametrically opposed point loads.

specimen are related to the corresponding strains by the generalized Hooke's Law (Timoshenko & Young 1962) as follows:

in the coating

$$\sigma_{1c} = \frac{E_c}{1 - \nu_c^2}(\varepsilon_{1c} + \nu_c\varepsilon_{2c}) \qquad (1)$$

$$\sigma_{2c} = \frac{E_c}{1 - \nu_c^2}(\varepsilon_{2c} + \nu_c\varepsilon_{1c}) \qquad (2)$$

in the substrate

$$\sigma_{1s} = \frac{E_s}{1 - \nu_s^2}(\varepsilon_{1s} + \nu_s\varepsilon_{2s}) \quad (3)$$

$$\sigma_{2s} = \frac{E_s}{1 - \nu_s^2}(\varepsilon_{2s} + \nu_s\varepsilon_{1s}) \quad (4)$$

where E is Young's modulus of elasticity, ν is Poisson's ratio, and the subscripts c and s denote the coating and substrate respectively. (Elastic behaviour is assumed.)

In general no simple stress ratio relationships can be inferred from these equations. In the case of a fully bonded coating, however, $\varepsilon_{1c} = \varepsilon_{1s}$ and $\varepsilon_{2c} = \varepsilon_{2s}$, and if in addition it is assumed that $\nu_c = \nu_s$ then it follows from equations (1) and (3) that

$$\frac{\sigma_{1c}}{E_c} = \frac{\sigma_{1s}}{E_s} \quad (5)$$

The well known stress solution (Den Hartog 1952) for this form of loading gives:

$$\sigma_{1c} = \frac{2P_c}{\pi d t_c} \quad (6)$$

and

$$\sigma_{1s} = \frac{2P_s}{\pi d t_s} \quad (7)$$

From equation (5), therefore

$$\frac{P_c}{E_c t_c} = \frac{P_s}{E_s t_s} \quad (8)$$

and since

$$P_s = P - 2P_c \quad (9)$$

it follows that

$$\frac{P_c}{E_c t_c} = \frac{P - 2P_c}{E_s t_s} \quad (10)$$

Rearranging equation (10)

$$P_c = \frac{P E_c t_c}{E_s t_s + 2E_c t_c} \quad (11)$$

and substituting into equation (9)

Nomenclature

d	diameter of specimen
E_c	Young's modulus of coating material
E_s	Young's modulus of substrate
P	load applied to specimen
P_c	portion of applied load carried by coat (P* load at failure of coating)
P_s	portion of applied load carried by substrate (P** load at failure of substrate)
t	thickness of specimen
t_c	thickness of coat
t_s	thickness of substrate
ε_{1c} ε_{2c}	horizontal and vertical strains in coating
ε_{1s} ε_{2s}	horizontal and vertical strains in substrate
ν_c	Poisson's ratio of coating
ν_s	Poisson's ratio of substrate
σ_{1c} σ_{2c}	horizontal and vertical stresses in coating
σ_{1s} σ_{2s}	horizontal and vertical stresses in substrate
σ_{fc}	fracture stress of coating
σ_{fs}	fracture stress of substrate

$$P_s = \frac{P E_s t_s}{E_s t_s + 2E_c t_c} \quad (12)$$

The tensile stresses (i.e. the horizontal stresses, normal to the loaded diameter) in the coating and substrate are obtained in terms of P from equations (6) and (7) in the forms.

$$\sigma_{1c} = \frac{2PE_s}{\pi d(E_s t_s + 2E_c t_c)} \quad (13)$$

$$\sigma_{1s} = \frac{2PE_c}{\pi d(E_s t_s + 2E_c t_c)} \quad (14)$$

Proceeding simply on a stress basis, the full load P* to cause fracture in the coating would be

$$P^* = \sigma_{fc}\frac{\pi d(E_s t_s + 2E_c t_c)}{2E_c} \quad (15)$$

where σ_{fc} is the tensile fracture stress of the coating. Similarly, the load P** to cause fracture in the substrate would be

$$P^{**} = \sigma_{fs}\frac{\pi d(E_s t_s + 2E_c t_c)}{2E_s} \quad (16)$$

where σ_{fs} is the tensile fracture stress of the substrate.

It must be emphasized that these equations are strictly valid only for the following conditions:

1. There is an intimate contact between the coating and the substrate ensuring that changes in the length of the vertical diameter of the coating and the substrate are the same.
2. The Poisson's ratios of the coating and substrate are equal.

The process of film coating is intended to produce an intimate contact between the coating and the substrate. Hence, in most cases the first of the above assumptions is valid and until either the coating or substrate fracture, the changes in length along the vertical diameter should be the same. After fracture, changes in dimensions are dependent upon the sequence of failure.

Unfortunately, Poisson's ratio values for pharmaceutical materials do not appear in the literature. Ridgway et al (1970) have used a value of 0·33 for substrates when deriving expressions for the indentation of tablet surfaces. For polymers, the value could be a little higher, (0·35 → 0·45) depending upon the temperature. It is considered that the possible small differences in Poisson's ratios would not seriously impair the usefulness of the above analysis as a guide in the understanding of the influence of the various variables.

The application of the analysis and the conclusions drawn are only valid up to the point of fracture of either coating or substrate. After this point the distribution of the applied load may change radically.

Practical significance

Hitherto, the evaluation of the influence of a coating on the mechnical strength of tablets had been undertaken largely on an empirical basis, the load necessary to break the coated tablet completely, being recorded. The changes in strength which occur as a result of coating are well recognized but the mechanism of these effects is not properly understood and reliable predictions cannot be made. The theoretical analysis outlined above has implications in the interpretation of experimental results and the design of test procedures.

A particularly significant inference follows directly from equations (15) and (16), namely that if

$$\frac{\sigma_{fc}}{E_c} > \frac{\sigma_{fs}}{E_s}$$

then $P^* > P^{**}$ i.e. the substrate fractures first and if

$$\frac{\sigma_{fc}}{E_c} < \frac{\sigma_{fs}}{E_s}$$

then $P^* < P^{**}$ i.e. the coating fractures first. (In view of the biaxial stress state along the loaded diameter, a simple interpretation of these equations in terms of a hypothetical 'fracture strain' is inappropriate.)

In neither case does the thickness of the substrate or coating have any influence on which fractures first; the first fracture location is determined solely by the ratio of tensile fracture strength to Young's modulus for the two materials.

Although the values of both tensile fracture stress and Young's modulus are dependent on the method of testing, certain generalizations can be made:

1. Film coating materials are usually flexible polymers, and will generally have a lower Young's modulus than the tablet substrate i.e. $E_c < E_s$.
2. Most polymer film coatings will have a higher value for tensile fracture strength than tablet substrates i.e. $\sigma_{fc} > \sigma_{fs}$.

To obtain an equivalent fracture stress to that of a typical film coating material (20 MN m^{-2}, Entwistle & Rowe 1979), the substrate would have to fracture at a load in excess of 10^3N (assuming normal tablet dimensions). Such a value is not attainable with normal unsintered tablets. Combination of these two effects makes the condition

$$\frac{\sigma_{fc}}{E_c} > \frac{\sigma_{fs}}{E_s}$$

the more likely, indicating that, in practically all cases of diametrical compression testing of film coated tablets, the substrate should fail first.

A first peak or discontinuity in the load/time curve was clearly observed by Fell et al (1979), followed by a second peak and often further multiple peaks when film-coated tablets were subjected to diametral compression. The former represents the failure of the substrate while the latter probably represent the successive stages in the collapse of the broken substrate surrounded by the intact coating. The final breaking load is not likely to represent the tensile failure of the coating but the complete collapse of the substrate and will inevitably be a poorly reproducible value due to the variable stress conditions in the system. Even though the coating may eventually fail (sometimes in tension) when the substrate has fractured it is not possible to apply a dependable stress analysis to determine the tensile fracture stress of the coating. Thus interpretation of this type of load/time curve remains problematic and the maximum breaking load is of little value.

The existence of a single peak in the load/time curve for some coated tablets suggests that in these cases coating and substrate fail at the same breaking load. Such an event could occur if

$$\frac{\sigma_{fc}}{E_c} \simeq \frac{\sigma_{fs}}{E_s}$$

a condition which is presumably possible, but highly unlikely. A close examination of the results of Fell et al (1979) reveals that coated tablets which fail with a single peak are those which have a high measured substrate/coating adhesion (e.g. tablets coated with a low molecular weight hydroxypropylmethyl cellulose (Pharmacoat 603)) and tablets which have a thin coating. The former effect is not fully understood. Tablet coatings which are thin are unlikely to provide an envelope of sufficient strength to carry the load, once failure of the substrate has occurred, and probably cannot remain intact to provide support for the broken core, resulting in a single failure load.

Further implications of equations (15) and (16) are that if the initial failure, whether of the substrate or coating, can be readily detected, then the variation of fracture load with coating or substrate thickness can be assessed. Thus for failure of the substrate first:

$$P^{**} = \sigma_{fs}\frac{\pi d t_s}{2} + \sigma_{fs}\,\pi d\frac{E_c}{E_s}t_c$$

i.e. a plot of P^{**} as a function of substrate thickness, t_s, at constant coating thickness should be linear, and the values of σ_{fs} and E_c/E_s can be determined from the slope and the intercept. Similarly for tensile failure of the coating first:

$$P^* = \sigma_{fc} \frac{\pi d}{2} \frac{E_s}{E_c} t_s + \sigma_{fc} \pi d \, t_c$$

i.e. a plot of P* as a function of coating thickness, t_c, at constant substrate thickness, should be linear, and the values of σ_{fc} and E_s/E_c can be determined from the slope and the intercept. It is important to realize that these relationships are only valid for the initial failure of either the substrate or the coating. There is no simple relationship linking thickness of either substrate or core with final, total breaking load of a load/time curve with multiple peaks.

For most systems in which the substrate fails before the coating, there is little hope of predicting the influence of coating characteristics on the fracture stress of the coating. If however it were possible to provide test conditions such that

$$\frac{\sigma_{fc}}{E_c} < \frac{\sigma_{fs}}{E_s}$$

i.e. the coating failed first, it should be possible to determine the fracture stress of the coating. This could be achieved by changing the substrate or alternatively changing the temperature and/or the strain rate of the diametral compression test to provide changes in E_c, E_s, σ_{fc} and σ_{fs}.

The analysis clearly establishes therefore that it is necessary to provide test conditions which allow recognition of the different sequence of failure and also suggests the means by which this sequence can be influenced. Tests which simply crush the specimen and record the total load are of little value for fundamental studies of strength changes induced by coating tablets, and do not clearly indicate the true mechanical characteristics of either core or coating.

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