The mechanical strength of film-coated tablets

J. T. FELL‡, R. C. ROWE* AND J. M. NEWTON†

Department of Pharmacy, University of Manchester, Manchester, M13 9PL

The mechanical strength of film-coated tablets has been assessed using the diametral compression test. The results show that the influence of the film is more complex than that suggested by Stern (1976). The film may increase the breaking load of the core itself by acting as a padding material during the test and also by filling in surface irregularities. The film may also have enough intrinsic strength and elasticity to hold the core together once it has broken. The maximum breaking load to completely fracture the coated tablet is related to film properties, but the relation is not a simple one.

One reason for film coating tablets is to increase their overall strength and resistance to attrition, thereby decreasing problems during high speed packaging. A knowledge of the factors affecting the strength of the film coating is therefore necessary in formulation and since it is generally accepted that film properties are affected by the method of casting (e.g. spraying conditions, solvents used) it is pertinent to study the film on the tablet surface. Film properties such as hardness and modulus of elasticity can be measured using a microindentation technique (Rowe 1976a; Porter & Ridgway 1977) but other mechanical properties can be assessed only by stressing the film coated tablet. Stern (1976) has shown that the increase in crushing strength of a film-coated tablet is directly proportional to the film thickness, but this finding has recently been disputed (Porter & Ridgway 1977). Rowe (1976b) has also shown that, although the crushing strength of a tablet coated with hydroxypropyl methyl cellulose increases with increasing molecular weight of the polymer, coating with a very low molecular weight polymer can result in a lower crushing strength than the uncoated tablet. This was thought to be due to the penetration of coating solution into the upper surface of the tablet, thereby disrupting the bonds between the particles in the surface layers. A further factor to be considered is that the film coating can act as a padding material between the tablet and the platen of the testing machine. This is known to affect the stress distribution over the tablet diameter and also the magnitude of the breaking load (Fell & Newton 1970; Addinall & Hackett 1964). It would appear, therefore, that the effect of film coatings on the crushing strength of tablets is not such a simple function as originally suggested by Stern (1976). We have extended these earlier studies with a view to understanding the failure mechanism in film-coated tablets.

MATERIALS AND METHODS

All the tablets used were taken from batches used in previous work (Fisher & Rowe 1976; Rowe 1976b, 1978). The tablets were prepared by compressing a standard placebo granule of 300 mesh lactose, granulated with starch paste and lubricated with 1% magnesium stearate, using an instrumented single punch tablet machine (Type F3, Manesty Machines Ltd.). The tablets were coated with a film formulation consisting of four parts hydroxypropyl methyl cellulose (different molecular weight grades of Pharmacoat—Shinetsu Chemical Co. Ltd., Japan, or Methocel 60HG—Dow Chemical Co. Ltd., U.S.A.) and one part ethyl cellulose (Grade N7—Hercules Powder Co. Ltd., U.S.A.) with 20% w/w glycerol as plasticizer. The formulations were all applied as a 2·5% w/v solution dissolved in a dichloromethane–methanol (70:30% v/v) solvent mixture using either a 6 inch diameter Wurster column or 24 inch 'Accelacota' (Manesty Machines Ltd.). For any set of comparative experiments, the batches used to prepare the coating formulations were kept constant, but different batches were sometimes used for experiments that were not directly comparable. Film thicknesses in excess of $50~\mu m$ were measured using a micrometer, those below $50~\mu m$ were calculated by extrapolation, knowing the relative amounts of polymer applied.

The mechanical strength of the uncoated and coated tablets was measured by the application of the diametral compression test (Fell & Newton 1970) using an Instron physical testing instrument at a compression rate of $0·013~mm~s^{-1}$. The tablets

* I.C.I. Pharmaceuticals Division, Alderley Park Cheshire, U.K.
† Department of Pharmacy, Chelsea College, London University, Manresa Road, London, SW3 6LX.
‡ Correspondence.

had previously been stored at room temperature and 50% R.H. for at least two weeks and the tests then carried out at the same time. Twenty samples were tested and the mean and standard deviation calculated.

RESULTS AND DISCUSSION

Initial studies showed that the coating process when carried out with the solvent alone had no effect on the mechanical strength of the tablet cores. The influence of films of different molecular weight polymers on the breaking loads of the tablets is shown in Table 1.

Table 1. The breaking loads of tablets coated with different molecular weight polymers.

Grade of HPMC with approx. no. av. mol. wt.	'1st peak' breaking load (N)		Maximum breaking load (N)	
	mean	s.d.	mean	s.d.
Uncoated core tablets*				
—	121·6	9·13	121·6	9·13
Pharmacoat 603*				
9 200	146·2	7·86	146·2	7·86
Pharmacoat 606				
11 300	159·9	13·61	161·9	13·04
Pharmacoat 615				
14 500	147·1	6·33	178·5	11·89
Methocel 60 HG viscosity 15				
14 500	145·2	4·31	212·9	16·75
Methocel 60 HG viscosity 21 000	139·3	10·18	210·9	19·77

* '1st peak' and maximum breaking load are identical (see Fig. 1a).
   The coating thickness for all the film formulations was 35 μm.

The chart recording from the Instron is a continuous plot of load applied against crosshead movement. For the core tablets, and tablets coated with the film formulation containing Pharmacoat 603, and most of those coated with the film formulation containing Pharmacoat 606, the type of trace obtained is shown in Fig. 1a, whereas the remainder of the coated tablets produce a trace as shown in Fig. 1b. The '1st peak' of the latter trace is due to the breaking of the core in tension, as can be shown by removal of the film and examination of the tablet core. Commercial testing instruments such as the Schleuniger, as used by Stern (1976), would not detect this difference in behaviour as only the final fracture point is determined. The remainder of the peaks, as shown in Fig. 1b, appear to be due to successive fractures of the broken core, the film being strong enough to hold the
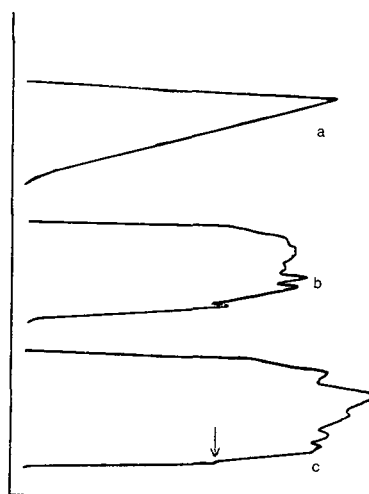

FIG. 1. The traces obtained from the Instron testing instrument during the testing of various types of tablets (see text). Ordinate: crosshead movement. Abscissa: Applied load.

fractured core together, until finally the film ruptures to allow relief of the stress. Because of the uncertain stress distribution leading to this final fracture, the results are interpreted as breaking loads, rather than calculating tensile strengths.

In all cases, the value of the 1st peak is significantly higher than the cores alone ($P = 0.05$), but is independent of the molecular weight of the polymer. However, if the maximum breaking load values are examined, there is an increase with increasing molecular weight of polymer.

The influence of coating thickness on the tablet breaking loads was studied using a film formulation containing Pharmacoat 606. The results are given in Table 2. For tablets with film thicknesses of 9 and 17 μm, the trace as shown in Fig. 1a is observed, whereas for thicker films (35, 70 and 105 μm), the trace shown in Fig. 1b is found. For very thick films (140 μm) a further trace as shown in Fig. 1c is observed, which exhibits a change of slope before the maxima. The maximum breaking load increases with an increase in film thickness, but the two are not linearly related. The '1st peak' however, is independent of the film thickness over the range studied.

When a tablet is subjected to diametral compression, failure will occur due to the tensile stresses set up within the tablet by a correctly controlled set of test conditions (Fell & Newton 1970). Failure will commence at a suitably orientated flaw, and as the tensile stresses are predominantly uniform along

Table 2. The influence of thickness of a film formulation containing Pharmacoat 606 on the breaking loads of tablets.

Film thickness (μm)	'1st peak' breaking load (N)		Maximum breaking load (N)	
	mean	s.d.	mean	s.d.
9*†	169·7	20·24	169·7	20·24
17*†	176·6	18·90	176·6	18·90
26*	179·5	14·87	206·0	20·24
35*	178·5	16·16	219·7	21·25
52*	176·6	10·81	246·2	24·95
70*	168·7	13·79	270·8	28·11
35+	154·0	7·17	175·6	13·20
70+	157·0	7·21	228·6	17·05
105+	155·0	10·37	260·9	15·30
140+	165·8	10·09	291·4	17·23

* Application by Wurster, breaking load of cores = 160·9 N.
+ Application by Accelacota, breaking load of cores = 121·6 N.
† 1st peak and Maximum breaking load are identical (see Fig. 1a).

Table 3. The 'padding effect' of a film formulation containing Methocel 60 HG viscosity 15 on the breaking loads of core tablets.

Specimen Type	Breaking load (N)	
	mean	s.d.
Coated core 1st peak value	145·2	4·31
Cores alone	121·6	9·13
Core alone with film as padding	131·5	9·55
Coated core, edges remaining	115·8	7·46
Coated core, faces remaining	136·4	4·52
Coating totally removed	113·6	7·15

Thickness of coating film was 35 μm.

the length of a cylindrical specimen (Rudnick et al 1963), this flaw could be in the body of the tablet, or at its surface. The use of soft padding materials between the tablet and the hard platens of the testing machine can ensure tensile failure for certain specimens (Fell & Newton 1970), but, because it changes the stress distribution within the tablet, it can also increase the magnitude of the load necessary to cause the tablets to break.

The application of a film coating to a tablet may influence its strength in several ways:

(a) The elastic nature of the film may allow it to act as a padding material and increase the breaking load of the core as described.

(b) The film may fill in irregularities in the surface of the tablet core reducing the possibility of fracture commencing at flaws in the surface.

(c) Having different mechanical properties from the core, the film may act as an envelope which has enough intrinsic strength to resist breakage even after the core itself has broken.

The effect of the film described in (c) has already been mentioned. To examine the padding influence of the film, tablets coated with the film formulation containing Methocel 60HG viscosity 15 were chosen, as the films could be easily removed without noticeable damage to the cores. Films were carefully removed from the faces of coated tablets, and interposed between the cores and the platens of the testing machine. Fresh films were used for each core broken. The results are given in Table 3. The use of the film as a padding material increases the

breaking load of the core, but not sufficiently to account for the value of the increase as measured by the '1st peak' value for the intact tablets. A further effect may be the influence of the film on the faces of the tablets, as tablets with the film around the edges removed, but with that on the faces remaining gave higher values than the cores alone (Table 3). Tablets with the coating totally removed gave significantly different results from the cores alone, and tablets with the film from the face of the tablet removed, but the edges left intact to act as padding, were significantly different from cores broken with padding. These last two results stress the importance of surface conditions on the load necessary to cause breakage of the tablets.

The results presented show that the influence of the coating on the strength of tablets is not simple, several effects being operative. The film can influence
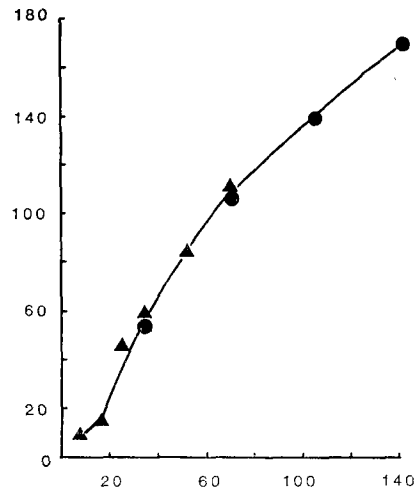

FIG. 2. The relation between film thickness (μm: abscissa) and the increase in maximum breaking load (N: ordinate) for core tablets coated with Pharmacoat 606. ▲ = coat applied by Wurster method. ● = coat applied by Accelacota.

the breaking load of the core itself (1st peak value), by acting as a padding and influencing the stress distribution during the diametral compression test. It may also act by changing the surface characteristics of the core and this, together with the padding effect, is largely independent of the film material and its thickness. It is valid, therefore, as has been done by Stern (1976), to subtract the maximum breaking load of the tablet from that of the core, to compare different films. This, however, is not simply an additive function as suggested by Stern, as is shown by the plot of increase in breaking load against film thickness, Fig. 2. The inflexions in the curve correspond closely to the breaking pattern changes as shown in Fig. 1a, b and c. This may well be due to changes in stress distribution within films of different thickness during testing. This result is different from that obtained by Stern showing that the influence of the film on the maximum breaking load of the core is not simply an additive function, and that film strength cannot be calculated from these results.

REFERENCES

Addinall, E., Hackett, P. (1964) Civ. Eng. Public Works Rev. 1250–1253
Fell, J. T., Newton, J. M. (1970) J. Pharm. Sci. 59: 688–691
Fisher, D. G., Rowe, R. C. (1976) J. Pharm. Pharmacol. 28: 886–889
Porter, S. C., Ridgway, K. (1977) J. Pharm. Pharmacol. 29: Suppl. 42P
Rowe, R. C. (1976a) Ibid. 28: 310–311
Rowe, R. C. (1976b) Pharm. Acta Helv. 51: 330–334
Rowe, R. C. (1978) J. Pharm. Pharmacol. 30: 343–346
Rudnick, W. C., Hunter, A. R., Holden, F. C. (1963) Mat. Res. and Standards 1: 283–289
Stern, P. W. (1976) J. Pharm. Sci. 65: 1291–1295