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EFFECT OF BINDER AND GEOMETRY OF TABLET ON RATE OF WEAR, HARDNESS AND TENSILE STRENGTH

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ABSTRACT

The relation of concentration of starch and povidone in tablets of Emcompress and Fast-Flo lactose and the relation of pressure applied to the tablets to wear rate constant, hardness and tensile strength are reported. The extent to which these parameters are changed by concentration and applied pressure is compared. The influence of shape on the wearability of flat face, flat face bevel edge bisect and standard convex tablets with and without a lubricant was studied.

INTRODUCTION

In tablet technology, a blend of pharmaceutical powders is commonly granulated with a binding solution. The incorporation of a binder increases the adhesiveness of the formulation and the mechanical strength of the tablet (1). The strength of pharmaceutical tablets, which must be sufficient to withstand processing and handling, may be expressed in various ways (2). Although hardness is a convenient and useful parameter for in-process control, it is an empirical property. Tensile strength is a property of the compressed material and is a basic parameter which maintains consistency of property if the size of the tablet is changed (3). The processing and handling of tablets subject them to attritive and abrasive stress in contrast to a compressive stress as measured by hardness and tensile strength. The purpose of the present report is to suggest that wearability tests can quantitatively express the strength of tablets in terms of wear rate constants and wear half lives and that they are useful in determining the effect of binders and the shape of the tablet on its resistance to processing and handling.

EXPERIMENTAL

The materials used and the preparation of tablets with a diameter of 1.275 cm have been described (4). Flat face, flat face bevel edge bisect and standard concave punches and dies were used. Hardness was measured by a Schleuniger 2E hardness tester. The tensile strength was measured by a Hounsfield tensiometer. Wearability expressed as a first-order wear rate constant and half life was determined using the wear tests previously described (4).

RESULTS AND DISCUSSION

Effect of Binder on Mechanical Strength. The addition of a binder increases the mechanical strength of a tablet. For a given applied pressure as shown in Figure 1 the hardness and the tensile strength of tablets of Emcompress and Fast-Flo lactose are increased as the concentration of povidone or starch is increased.

The relationship of hardness and tensile strength of tablets of Emcompress and Fast-Flo lactose granulated with povidone and starch to applied pressure is shown in Figures 2 and 3. Only for tablets of Emcompress and tablets of Emcompress granulated with 1% starch or povidone was there no statistical difference (t-test) in hardness and tensile strength as the applied pressure varied from 390-1960 kg/cm^2. At concentrations of binder exceeding 1% an increase in applied pressure produced a tablet having a greater hardness and tensile strength.

The mechanical strength of tablets of Emcompress was increased to a slightly greater extent by the addition of 9%

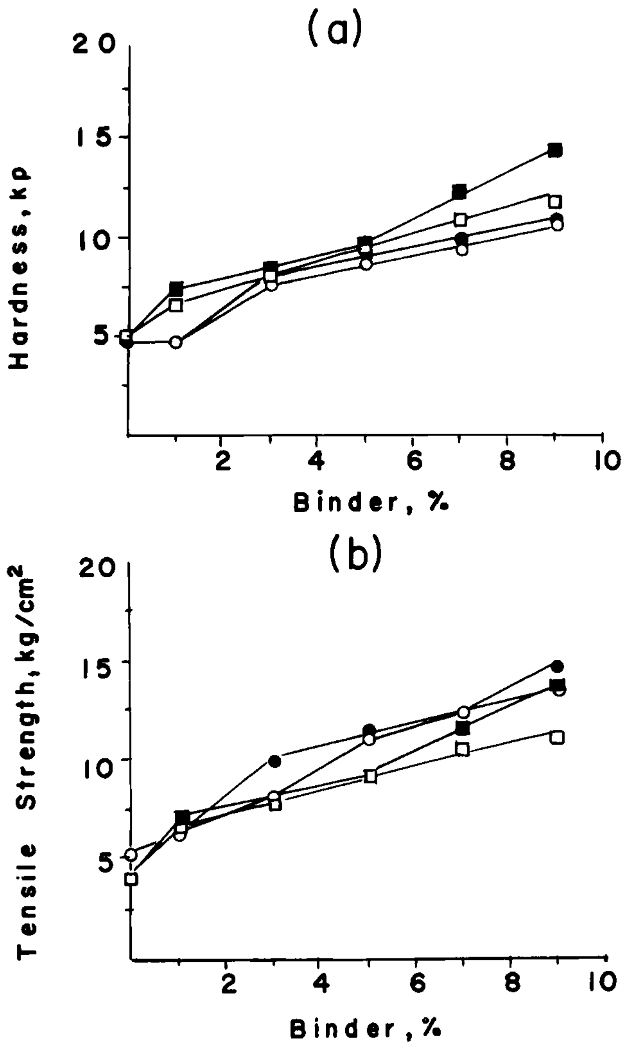

FIGURE 1

The effect of concentration of binder on hardness and tensile strength of flat face tablets compressed at 390 kg/cm^2.
Key: (●) Emcompress with starch; (○) Emcompress with povidone; (■) Fast-Flo Lactose with starch; and (□) Fast-Flo Lactose with povidone.

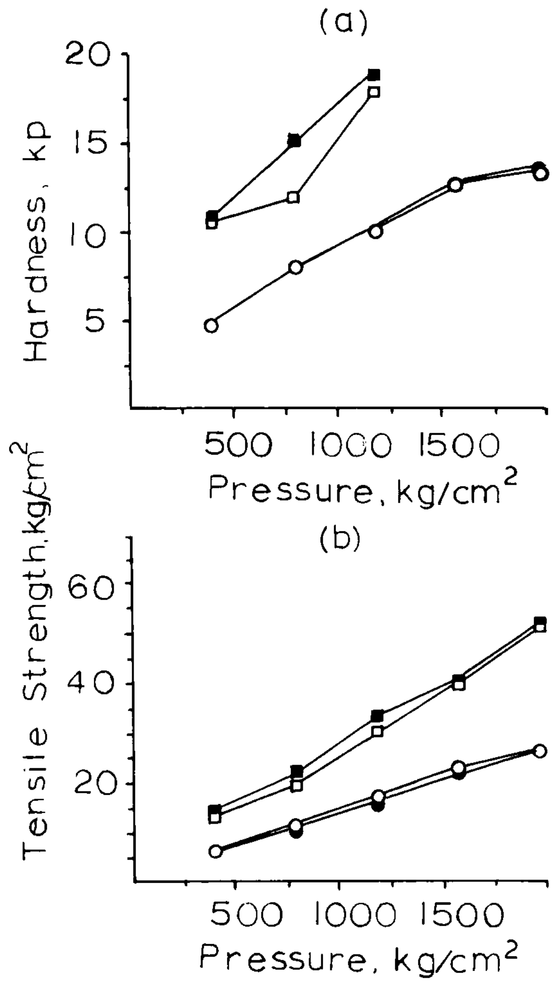

FIGURE 2

The relationship of hardness and tensile strength to applied pressure for flat face tablets of Emcompress containing 1 and 9% binder. Key: (●) 1% starch; (○) 1% povidone; (■) 9% starch; and (□) 9% povidone.

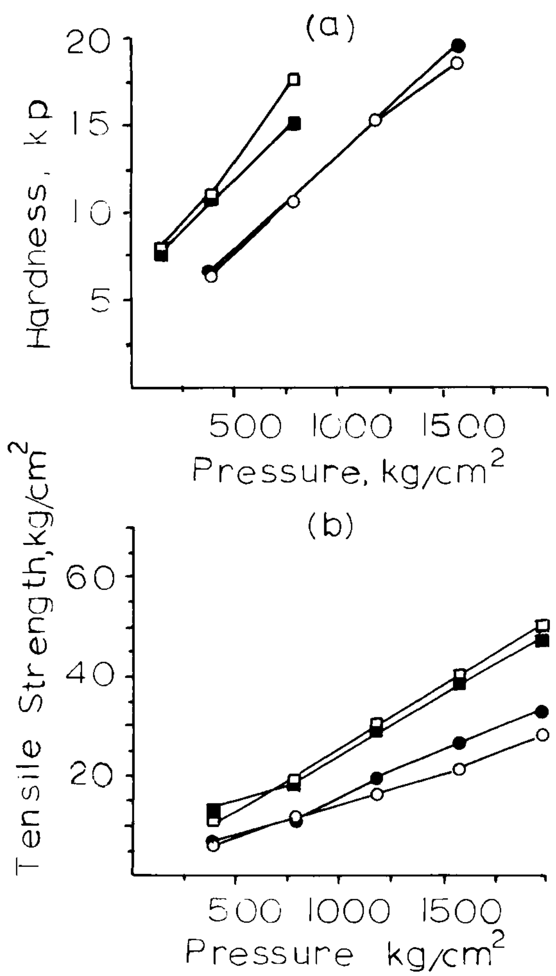

FIGURE 3

The relationship of hardness and tensile strength to applied pressure for flat face tablets of Fast-Flo Lactose containing 1 and 9% binder. Key: (●) 1% starch; (○) 1% povidone; (■) 9% starch; and (□) 9% povidone.

TABLE 1

Wear Rate Constants and Wear Half Lives of Tablets of Emcompress Incorporating Various Concentrations of Starch Compressed at 390 kg/cm²

Starch, %	Wear Time, min	Weight Remaining, %	r^2	Wear Process	10^4 Wear Rate Constant, min^{-1}	Half Life, min
0	2-95	96.9-49.2	0.999	k_1	72.24	92
1.0	2-6	98.2-96.6	0.995	k_1	41.07	
	6-10	96.6-94.2	0.997	k_2	62.90	
	10-35	94.2-83.2	0.999	k_3	49.52	
	35-180	83.2-49.8	0.999	k_4	53.21	180
3.0	2-10	98.9-96.6	0.998	k_1	29.67	
	10-25	95.7-94.8	0.996	k_2	9.45	
	25-90	94.8-85.9	0.998	k_3	15.24	
	90-500	85.9-51.8	0.999	k_4	12.27	526
5.0	5-30	98.9-95.2	0.998	k_1	15.05	
	30-120	95.2-87.0	0.998	k_2	9.78	
	120-500	87.0-66.6	0.999	k_3	7.12	899
7.0	10-30	98.2-95.9	1.000	k_1	11.84	
	30-320	95.9-78.6	0.999	k_2	6.69	
	320-500	78.6-71.1	0.999	k_3	5.69	1115
9.0	5-30	99.1-96.7	0.996	k_1	9.64	
	30-100	96.7-92.5	0.997	k_2	6.45	
	100-220	92.5-87.3	0.998	k_3	4.79	
	220-500	87.3-78.7	0.996	k_4	3.76	1698

starch than by 9% povidone, and the mechanical strength of tablets of Fast-Flo lactose was increased to a slightly greater extent by the addition of povidone than by the addition of starch. This suggests that the solubilities of the material and the binder play a role in determining tablet strength.

The addition of a binder that confers plastic characteristics to a material should increase the resistance to wear. The ln W/W_o of tablets of Emcompress containing from 1-9% starch and compressed at 390 kg/cm² was plotted against wear time in

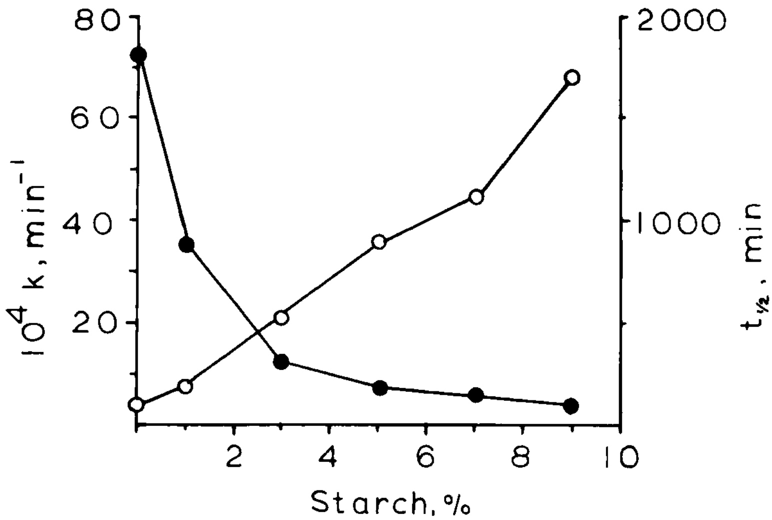

FIGURE 4

The effect of concentration of starch on wearability of flat face tablets of Emcompress compressed at 390 kg/cm². Key: (●) major wear rate constant; and (○) wear half-life.

the shaking wear test, and the first-order wear rate constant was determined from the slope (4) and is given in Table 1.

As shown in Figure 4 the wearability of the tablets is significantly decreased by the incorporation of concentrations of starch exceeding 3%. The relationship between wear half life and concentration of starch approaches linearity. The strengthening effect of the addition of starch on wearability of tablets of Emcompress is greater than that on hardness and tensile strength as shown in Table 2. As the concentration of starch is increased from 1.0, 3.0, 5.0, 7.0, to 9.0%, the hardness of tablets of Emcompress is increased by a factor of 1.02, 1.72, 1.94, 2.13 and 2.30; the tensile strength of tablets is increased by a factor of 1.19, 1.92, 2.19, 2.35 and 2.83; and the wear half-life is increased by a factor of 1.96, 5.72, 9.77, 12.12 and 18.46, respectively. The incorporation of starch by wet granulation has a greater effect on decreasing the wearability of tablets than on

TABLE 2

Effect of Binders on Mechanical Characteristics of Tablets Compressed at 390 kg/cm^2

Material	Ratio of Characteristic of Tablet Containing a Binder to That of the Tablet Containing No Binder			
	Hardness	Tensile Strength	Wear Rate Constant	Wear Half Life
Emcompress				
1% Starch	1.02	1.19	0.73	1.96
3% Starch	1.72	1.92	0.17	5.72
5% Starch	1.94	2.19	0.10	9.77
7% Starch	2.13	2.35	0.08	12.12
9% Starch	2.30	2.83	0.05	18.46
1% Povidone	1.00	1.23	1.00	1.00
9% Povidone	2.25	2.58	0.06	15.17
Fast-Flo Lactose				
1% Starch	1.32	1.73	0.42	1.98
9% Starch	2.14	3.32	0.14	6.95
1% Povidone	1.26	1.54	0.70	1.32
9% Povidone	2.20	2.70	0.16	5.41

increasing their hardness and tensile strength. This data indicate that the wear rate constant and wear half life are useful parameters in evaluating the resistance of a tablet to processing and handling and that they are not a measure of the same properties as hardness and tensile strength.

The ln W/W_o of tablets of Emcompress and tablets of Fast-Flo lactose containing 1.0 and 9.0% starch and povidone and compressed at 390 kg/cm^2 was plotted against wear time in the shaking wear test, and the first-order wear rate constant was determined from the slope and is given in Table 2 and 3. As seen

TABLE 3
Wear Rate Constants and Wear Half Lives of Tablets of Fast-Flo Lactose Incorporating Starch or Povidone Compressed at 390 kg/cm^2

Binder, %	Wear Time, min	Weight Remaining, %	r^2	Wear Process	10^4 Wear Rate Constant, min^{-1}	Half Life, min
None	0-110	100-50.2	1.000	k_1	62.72	110
1% Starch	2-20	98.0-88.4	0.999	k_1	58.22	
	20-60	88.4-76.7	0.997	k_2	35.34	
	60-220	76.7-50.3	0.999	k_3	26.38	220
9% Starch	5-20	98.2-95.2	0.998	k_1	20.69	
	20-50	95.2-90.8	0.996	k_2	15.92	
	50-100	90.8-85.9	0.999	k_3	10.49	
	100-500	85.9-55.9	1.000	k_4	8.74	772
1% Povidone	0-25	100.0-85.8	0.998	k_1	60.57	
	25-150	85.8-49.2	0.999	k_2	44.05	147
9% Povidone	5-20	97.9-94.4	0.997	k_1	24.34	
	20-100	94.4-83.6	0.995	k_2	15.01	
	100-500	83.6-55.6	0.999	k_3	10.09	600

in Table 2 the incorporation of 1.0% povidone has no effect on hardness and wearability of tablets of Emcompress compressed at 390 kg/cm^2.

The incorporation of 1.0% starch and povidone increases the wear half-life of tablets of Fast-Flo lactose by a factor of 2.0 and 1.3, respectively. The incorporation of 9.0% starch and povidone increases the wear half life of Fast-Flo lactose by a factor of 6.95 and 5.4, respectively. The resistance to wear of tablets of Fast-Flo lactose is greater than that of Emcompress, but the resistance to wear of Emcompress containing 9.0% starch and povidone is greater than that of Fast-Flo lactose containing the same concentration of binders.

Geometric Shape of Tablet. The flat face tablet used in previous reports (4) had a wear rate constant associated with its

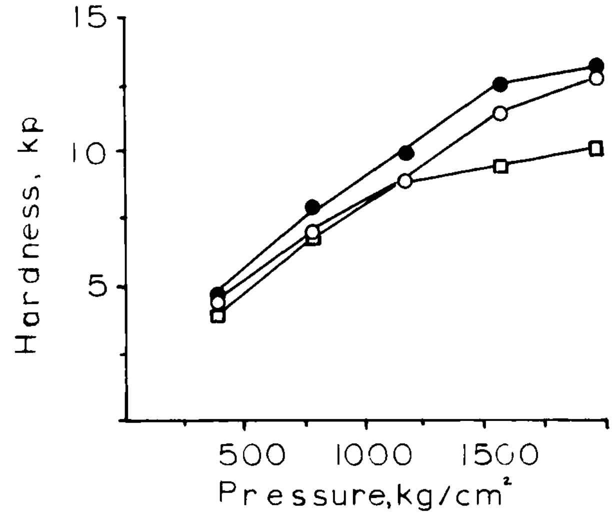

FIGURE 5

The relationship of hardness of various shaped tablets of Emcompress to applied pressure. Key: (●) flat face; (○) bevel edge bisect; and (□) standard convex tablet.

sharp edge. To evaluate which commonly used shape of tablet would be most resistant to processing and handling the wearability of flat face, flat face bevel edge bisect and standard convex tablets was studied. The relationship of hardness of tablets of Emcompress compressed at various applied pressures by flat face, flat face bevel edge bisect, and standard concave punches and die sets is shown in Figure 5. The flat faced tablet is the hardest. A similar relationship is shown in Figure 6 for tablets compressed of Emcompress blended with 1% magnesium stearate. The flat face tablet is the hardest, and the tablets compressed with a flat face bevel edge bisect and a standard concave punch and die set have essentially the same hardness.

The ln W/W_o was plotted against wear time in the rotating wear test for Emcompress compressed at 390 kg/cm^2 into various shaped tablets and the first-order wear rate constant was evaluated from the slope and is given in Table 4. The rotating

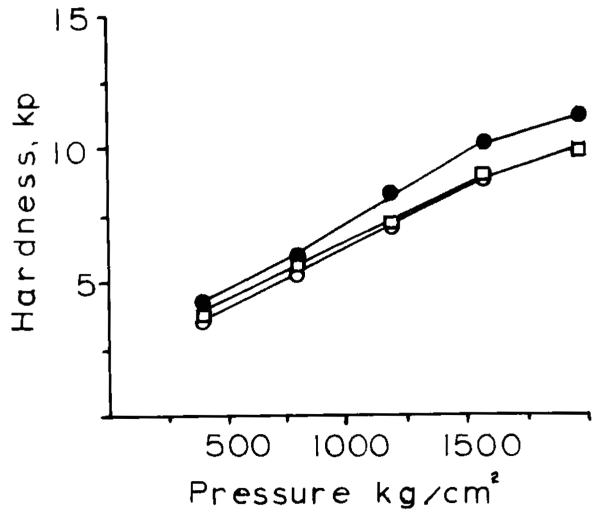

FIGURE 6

The relationship of hardness of various shaped tablets of Emcompress containing 1% magnesium stearate to applied pressure. Key: (●) flat face; (○) bevel edge bisect; and (□) standard convex tablet.

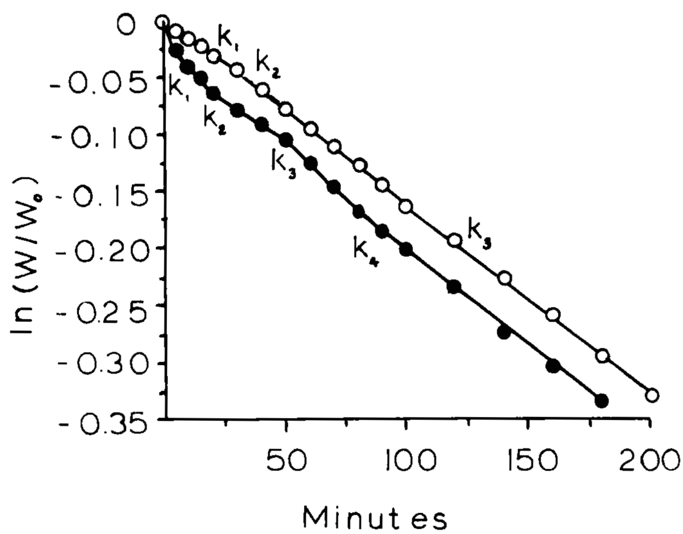

FIGURE 7

The relationship of natural logarithm of weight fraction of tablet to wear time in rotating wear test of Emcompress tablets compressed at 390 kg/cm^2. Key: (●) flat face tablet; and (○) standard convex tablet.

TABLE 4

Wear Rate Constants and Wear Half Lives of Tablets of Emcompress Compressed at 390 kg/cm^2 into Tablets of Various Geometric Shapes

Shape	Wear Time, min	Weight Remaining, %	r^2	Wear Process	10^4 Wear Rate Constant, min^{-1}	Half Life, min
Flat-face	5-20	97.4-93.8	0.997	k_1	24.69	
	20-50	93.8-90.1	0.997	k_2	13.16	
	50-80	90.1-84.5	0.999	k_3	21.31	
	80-380	84.5-50.3	1.000	k_4	17.30	385
Bevel edge	0-10	100-98.8	1.000	k_1	12.07	
	10-100	98.2-82.2	0.999	k_2	20.74	
	100-370	82.2-50.7	1.000	k_3	17.85	378
Standard convex	0-20	100-97.0	0.998	k_1	15.03	
	20-120	97.0-82.4	0.999	k_2	16.58	
	120-380	82.4-50.6	0.999	k_3	18.87	389

TABLE 5

Wear Rate Constants and Wear Half Lives of Tablets of Emcompress Incorporating 1% Magnesium Stearate Compressed at 390 kg/cm^2 into Tablets of Various Geometric Shapes

Shape	Wear Time, min	Weight Remaining %	r^2	Wear Process	10^4 Wear Rate Constant, min^{-1}	Half Life, min
Flat face	10-230	94.3-48.9	0.999	k_1	29.48	221
Bevel edge	0-10	100-96.9	0.997	k_1	31.38	
	15-150	95.0-49.3	1.000	k_2	48.76	146
Standard convex	0-70	100-84.6	0.999	k_1	23.80	
	70-160	84.6-65.2	0.999	k_2	29.04	
	160-230	65.2-49.1	1.000	k_3	40.87	225

wear half lives are essentially the same; however, the initial part of the wear process is different as illustrated by the example in Figure 7 and the differences in the wear rate constants in Table 4. During the initial 10 minutes of wear, the weight loss from flat face, flat face bevel edge bisect and standard convex tablets is 3.9, 1.2 and 1.6%, respectively. At a wear time of 300 minutes the weight loss of flat face, flat face bevel edge bisect and standard convex tables is 42.3, 42.7 and 40.9%, respectively. The flat faced tablet has the least wear resistance initially.

Similar procedures and treatment of the data for tablets of Emcompress incorporating 1% magnesium stearate compressed at 390 kg/cm^2 into tablets of various shapes produced the wear rate constants and half lives given in Table 5. The rotating wear half life of flat face and standard convex tablets are the same. The rotating wear half life of flat face bevel edge bisect tablet is shortened to a greater extent than the other shapes although the hardness is approximately the same.

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