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EFFECT OF LUBRICANTS ON TENSILE STRENGTHS OF TABLETS

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ABSTRACT

The effect of concentration of lubricant on the axial and radial tensile strengths of tablets was determined for four directly compressible pharmaceutical materials: anhydrous lactose, aspirin, microcrystalline cellulose, and dibasic calcium phosphate dihydrate. The lubricants investigated were: hydrogenated vegetable oil, magnesium stearate, polyethylene glycol 4000, stearic acid, and talc. For plastic materials the tensile strengths were reduced as the concentration of the lubricant was increased. For brittle material the tensile strength was not changed significantly as the concentration of lubricant was increased.

INTRODUCTION

Shotton and Lewis (1) observed the effect of lubricants on the crushing strength of tablets. As the concentration of

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lubricant was increased for aspirin, sodium chloride and hexamine the crushing strength was decreased rapidly to a constant value, but with sucrose the percent of the lubricant had no effect on crushing strength. Tablets of compressible starch and sodium chloride were reported to have an increase in crushing strength as the concentration of colloidal silica was increased (2). Alkaline stearates decreased the hardness of tablets containing compressible starch (3). Magnesium lauryl sulfate reduced tablet strength less than magnesium stearate (4). Juslin and Krogerus (5) found that in general increasing the quantity of lubricants resulted in a reduction of tablet strength.

It appears that the effect of a lubricant on mechanical strength depends on the bonding mechanism. The strength of a tablet depends on the area of intimate contact between the particles and the adhesive strength over this area. The strongest bonds are formed between clean surface so the addition of a lubricant interferes by acting as a physical barrier between particles for a material which undergoes plastic and/or elastic deformation. For materials, which are brittle and fragment, new clean surfaces are formed during compression, and the lubricant does not interfere as it does for a plastic material so that a stronger tablet is formed.

Four directly compressible pharmaceutical materials with various compressional characteristics were selected for this study. The effect of various concentrations of five lubricants

on the axial and radial tensile strengths of tablets compressed from these material was investigated.

EXPERIMENTAL

The lubricants used were: hydrogenated vegetable oil[1], magnesium stearate NF, polyethylene glycol 4000 NF, stearic acid NF, and talc USP. The directly compressible materials used were: anhydrous lactose[2], aspirin USP, microcrystalline cellulose[3], and dibasic calcium phosphate dihydrate[4]. Each lubricant was passed through a 60-mesh sieve just prior to blending for 20 minutes in a twin shell blender with a 60/80-mesh size fraction of the directly compressible material. An appropriate weight of the blend to produce tablets from 0.3 to 0.5 cm thick was compressed for 5 seconds by means of 1.275-cm flat-faced punches and die fitted to a hydraulic press[5] at a force depending on the properties of the materials. For blends that did not contain a lubricant the die wall was prelubricated with 5% magnesium stearate in acetone. At least 72 hr elasped between tablet compression and measurement of tablet strength to allow for any stress relaxation. The method of measurement of the axial tensile strength (σ_z) and the radial tensile strength (σ_x) of tablets by a tensiometer[6] has been described (6). The mean force of tensile failure of 10 tablets was used to calculate the tensile strength. Standard deviation bars for tensile strength are drawn in the figures.

RESULTS AND DISCUSSION

Brittle Material. The strength of compacts of brittle materials, which fragment during compression, are little affected by the addition of a lubricant because new, clean surfaces produced by fragmentation are available for bonding. Dibasic calcium phosphate is consolidated by brittle fracture (7). As indicated by the unchanged values of tensile strengths shown in Fig. 1 for concentrations of lubricant as great at 3 percent, magnesium stearate does not interfere with bonding of dibasic calcium phosphate dihydrate at a compressional force of 2,268 kg.

In a single punch tablet press the transmission of pressure within the die cavity is not uniform during tablet compression. It has been reported that the distortion of granules expressed as the ratio of the vertical to lateral dimension is of the order of 0.6 (8). Train (9) has presented contours of the pressure and density distributions in compacts. A region of higher pressure would have a higher density, a lower porosity and a greater mechanical strength than a region of lower pressure. Although oversimplified the pressure may be considered as an axial pressure causing compression of the granules and a radial pressure exerted on the die wall. During compression the friction between the die wall and the material tends to resist consolidation. There is also a logarithmic decrease of applied pressure down the length of the tablet resulting in a poorly compacted region having a low mechanical strength adjacent to the stationary punch (10). Thus, a tablet lacking in a uniform

density is produced, and the axial tensile strength may be less than the radial tensile strength (Fig. 1).

As the axial and radial tensile strengths of dibasic calcium phosphate tablets are unchanged by the addition of magnesium stearate, mechanical weakness and/or capping is not promoted by the addition of magnesium stearate in the concentrations studied. A similar result was obtained at compressional forces of 454, 1,134 and 3,042 kg.

The difference in distribution of compressional force during compression, bonding and density within a tablet produce a nonhomogeneous tablet possessing nonuniformity of tensile strengths. If the axial tensile strength is compared to the radial strength, and they are equal (e.g., $\sigma_z/\sigma_x = 1$), the bonding in both axes is equally strong, and the probability of the homogeneous tablet breaking in one axis would be no greater than in any other axis. If the axial tensile strength were much weaker than the radial tensile strength, the tablet would more readily break and/or cap in that plane. Thus, the ratio σ_z/σ_x could be used as an index of capping. The ratio would be unity for a homogeneous tablet and would decrease toward zero as the homogenity became progressively less (6).

In concentrations as great as 8 percent of lubricant the addition of stearic acid, hydrogenated vegetable oil[1] and talc does not markedly effect the tensile strengths and bonding of dibasic calcium phosphate dihydrate tablets. As shown in Table 1 from 0.5 to 4% lubricant the values of σ_z/σ_x changes approxi-

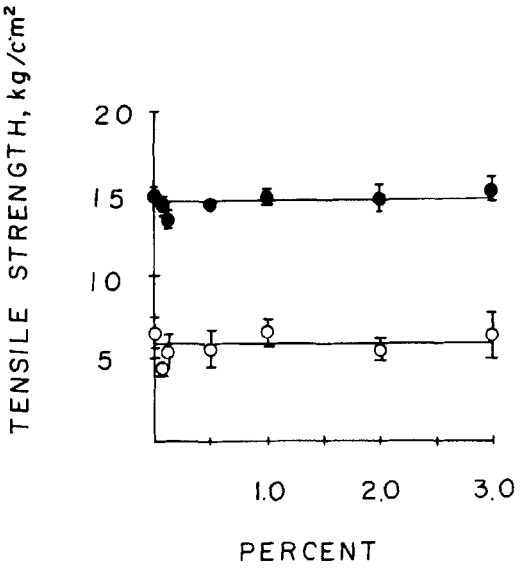

FIGURE 1

The effect of concentration of magnesium stearate on the tensile strength of dibasic calcium phosphate dihydrate tablets compressed at 2,268 kg. Key: ○, axial; and ●, radial.

mately 11, 7 and 3.5 percent, respectively, for stearic acid, hydrogenated vegetable oil[1] and talc.

Plastic Material. The strength of a tablet depends on the area of contact between the particles. The addition of a lubricant interferes with bonding between particles; and in addition to the formation of a physical barrier the lubricant reduces the amount of clean reactive surface produced by shear at the sliding contact areas between particles (11). A tablet of a material, which is plastically deformed, will be weakened mechanically to a greater extent by a lubricant than a material which is fragmented.

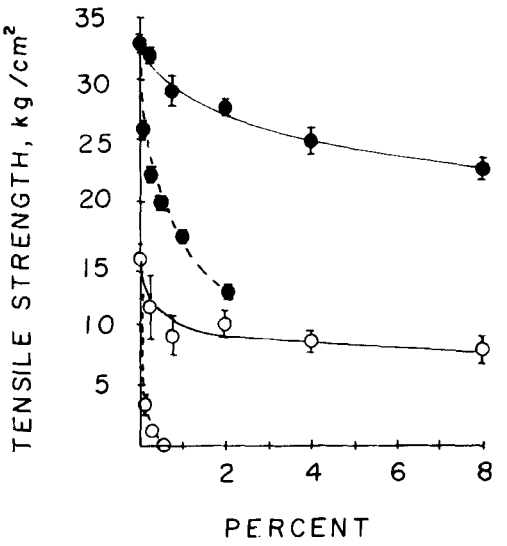

FIGURE 2

The effect of concentration of magnesium stearate and stearic acid on the tensile strengths of microcrystalline cellulose tablets compressed at 454 kg. Key: ○ , axial; ● , radial; —— , stearic acid; and - - - , magnesium stearate.

A tablet of microcrystalline cellulose, whose binding contact occurs primarily through plastic flow becomes mechanically weakened by lubricants (12). As shown in Fig. 2 the addition of magnesium stearate markedly decreases the axial and radial tensile strength of the tablet compressed at a force of 454 kg (at 0.5% magnesium stearate the axial tensile strength was reduced almost 100%). A similar result was obtained when stearic acid, hydrogenated vegetable oil[1], talc or polyethylene glycol was added to microcrystalline cellulose. As shown in Table 1 the value (0.47) of σ_z/σ_x for a microcrystalline cellulose tablet was decreased by the addition of a lubricant. The

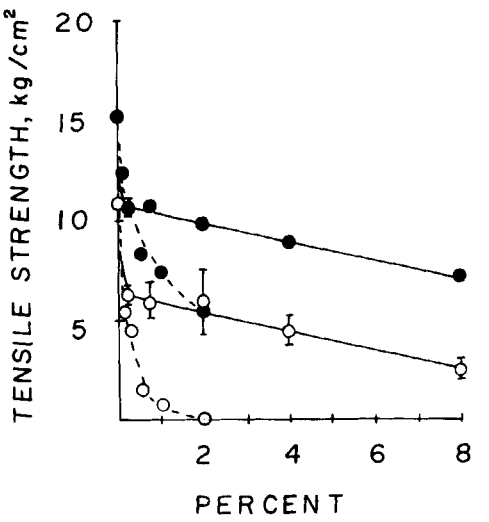

FIGURE 3

The effect of concentration of magnesium stearate and stearic acid on the tensile strengths of aspirin tablets compressed at 1,361 kg. Key: ○ , axial; ● , radial;—— , stearic acid; and - - - , magnesium stearate.

small value (0.1) of σ_z/σ_x for microcrystalline cellulose tablets containing magnesium stearate indicated capping is a potential problem, and the larger values (~0.34) with stearic acid, hydrogenated vegetable oil[1] or talc with microcrystalline cellulose suggests capping is less probable.

With aspirin compressed at 1,361 kg the increase in the concentrations of magnesium stearate markedly decreases the tensile strengths (Fig. 3). For example, at 2% magnesium stearate the axial and radial tensile strength are reduced 97 and 64%, respectively. The rate of decrease of tensile strengths is greater for magnesium stearate than for the other lubricants studied. As shown in Table 1 the low value of σ_z/σ_x reflects

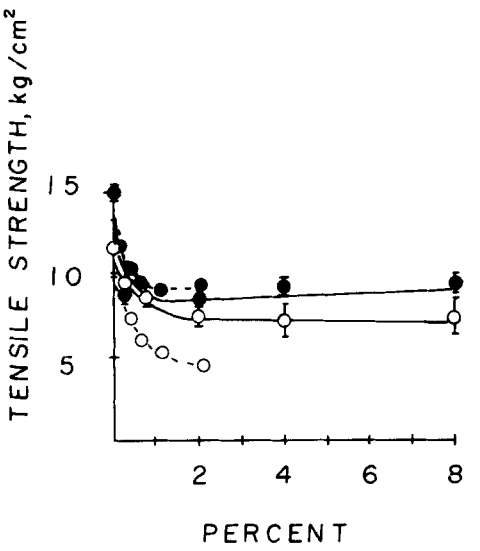

FIGURE 4

The effect of concentration of magnesium stearate and stearic acid on the tensile strengths of anhydrous lactose tablets compressed at 907 kg. Key: ○ , axial; ● , radial; —— , stearic acid; and - - - , magnesium stearate.

the very weak axial bonding and indicates that capping is likely if magnesium stearate is used as a lubricant.

When stearic acid, hydrogenated vegetable oil[1], talc or polyethylene glycol was added to aspirin, the tensile strengths were decreased to a lesser extent than with the addition of magnesium stearate. For example, at 8.0% hydrogenated vegetable oil[1] the axial and radial tensile strength were reduced 20 and 25%, respectively. However, the high values of σ_z/σ_x as shown in Table 1 did not markedly decrease indicating that although the tablets were mechanically weaker, capping was not promoted.

TABLE 1. Influence of Concentration of Lubricant on the Ratio of the Axial Tensile Strength to the Radial Tensile Strength of a Tablet

Lubricant	σ_z/σ_x							
	Percent							
	0	0.10	0.25	0.5	1.0	2.0	4.0	8.0
	Dibasic Calcium Phosphate[a]							
Magnesium stearate	0.44	0.40[e]	-	0.39	0.44	0.38	-	-
Stearic acid	0.44	-	0.55	-	0.47	0.44	0.61	0.53
Hydrogenated vegetable oil[f]	0.44	-	-	0.46	0.50	0.50	0.49	0.59
Talc	0.44	-	-	0.51	0.52	0.53	0.53	0.59
Polyethylene glycol	0.44	-	-	0.58	0.54	0.57	0.60	0.69
	Microcrystalline Cellulose[b]							
Magnesium stearate	0.47	-	0.04	0.10	-	-	-	-
Stearic acid	0.47	-	0.36	-	-	0.36	0.34	0.35
Hydrogenated vegetable oil	0.47	-	-	0.34	0.34	0.34	0.33	0.34
Talc	0.47	-	-	0.34	0.34	0.36	0.34	0.34
Polyethylene glycol	0.47	-	-	0.25	0.22	0.23	0.22	0.16

			Aspirin[c]					
Magnesium stearate	0.72	0.45	0.43	0.23	0.12	0.05	-	-
Stearic acid	0.72	-	0.59	-	-	0.60	0.51	0.35
Hydrogenated vegetable oil	0.72	-	-	0.75	0.78	0.71	0.70	0.77
Talc	0.72	-	-	0.71	0.75	0.71	0.67	0.63
Polyethylene glycol	0.72	-	-	0.81	0.70	0.64	0.68	0.64
			Anydrous Lactose[d]					
Magnesium stearate	0.78	0.86	0.72	0.62	0.59	0.47	-	-
Stearic acid	0.78	-	1.08	-	-	0.87	0.77	0.79
Hydrogenated vegetable oil	0.78	-	-	0.94	1.02	0.89	0.99	0.94
Talc	0.78	-	-	1.06	0.93	0.88	0.90	-
Polyethylene glycol	0.78	-	-	1.03	1.15	1.11	0.98	0.94

Compressional force: [a]2,268 kg, [b]454 kg, [c]1,361 kg, [d]907 kg; [e]0.125%; [f]Lubritab, Edward Mendell Co.

With anhydrous lactose compressed at 907 kg the addition of increased concentrations of lubricants decreased the axial and radial tensile strengths (Fig. 4). Again magnesium stearate reduced the tensile strengths to the greatest extent. For example, at 2% magnesium stearate the axial and radial tensile strength was reduced 63 and 38%, respectively. As shown in Table 1 the values of σ_z/σ_x were higher for lactose tablets containing stearic acid, hydrogenated vegetable oil[1], talc and polyethylene glycol than the value (0.78) for a lactose tablet. This indicates a strengthening in the axial plane so capping would be unlikely.

Lubricants. Magnesium stearate is probably the most effective and commonly used lubricant in tableting, and it may be used with brittle materials in excess of the usually employed concentrations of a lubricant with no detrimental effect on the strength of the tablet (Fig. 1). As demonstrated with microcrystalline cellulose, the addition of magnesium stearate decreases the tensile strength. In selecting a lubricant to be used with plastic materials it should be realized that magnesium stearate may interfere with bonding and produce a tablet of insufficient mechanical strength.

Stearic acid, hydrogenated vegetable oil[1], talc and polyethylene glycol may be used in concentrations as great as 8% as lubricants for brittle materials with only a slight to moderate change in tensile strength.

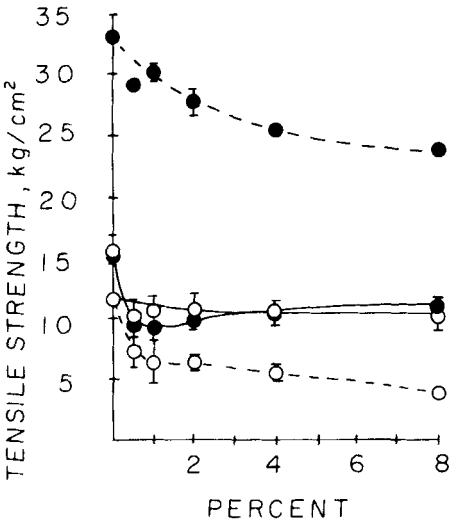

FIGURE 5

The effect of concentration of polyethylene glycol 4000 on the tensile strengths of anhydrous lactose tablets compressed at 907 kg and on microcrystalline cellulose tablets compressed at 454 kg. Key: ○ , axial; ● , radial; —— , lactose; and - - - , microcrystalline cellulose.

With the plastic materials studied stearic acid and hydrogenated vegetable oil[1] decrease the tensile strength considerably as the concentration is increased to 2%, and then the further addition of lubricant from 2 to 8% decreases the tensile strength to a lesser degree (~20%) and has no significant effect of the values of σ_z/σ_x (Table 1). Hydrogenated vegetable oil[1] interferes less with bonding, provides a mechanically strong tablet, and based on the data obtained in this study is recommended as a lubricant for plastic materials.

With aspirin and lactose as the concentration of talc is increased to 2% the tensile strength is decreased considerably,

and then the further increase in concentration to 8% of talc moderately (~20%) decreases the tensile strength and has no significant effect on the values of σ_z/σ_x. With microcrystalline cellulose the tensile strengths are decreased by approximately the same differential as the talc is increased to 8%.

The behavior of polyethylene glycol is less consistent than the other lubricants. With aspirin and anhydrous lactose (Fig. 5) as the concentration of polyethylene glycol is increased to 2% the tensile strength is decreased, and then the further addition of polyethylene glycol to 8% does not significantly change the tensile strength. With microcrystalline cellulose increasing the concentration of polyethylene glycol up to 8% steadily decreases the tensile strength (Fig. 5)

ACKNOWLEDGEMENTS

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FOOTNOTES

[1]Lubritab, Edward Mendell Co., Carmel, NY

[2]Lactose for Direct Tableting, Humko-Sheffield, Memphis, TN

[3]Avicel PH 102, FMC Corp., Philadelphia, PA

[4]Emcompress, Edward Mendell Co., Carmel NY

[5]Carver press, model C, Menomonee Falls, WI

[6]Hounsfield Tensometer, Type W, Tensometer Ltd., Croydon, England

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