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EFFECT OF TABLET LUBRICANTS ON AXIAL AND RADIAL WORK OF FAILURE

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ABSTRACT

During diametral compression and axial tensile strength testing force-displacement curves were obtained for tablets of microcrystalline cellulose. The area under the curve, termed work of failure, was determined by planimetry. For each of the five lubricants studied as the concentration of the lubricant was increased in the tablet, the work of failure was considerably less. The effect was especially marked in the axial plane.

INTRODUCTION

Rees and coworkers (1, 2) appear to be the first researchers to have calculated the work of failure of pharmaceutical tablets from the area of the applied force-displacement curve of tensile strength measurements. They suggested that the work of failure provides a basis for the comparison of the friability or failure of tablets as tablets of identical tensile strength prepared from different formulations may vary in their resistance to failure.

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In this study the effect of concentration of lubricant on the failure of tablets of microcrystalline cellulose was measured in terms of the work of axial and the work of radial failure. For microrystalline cellulose the work of axial failure was considerably less than the work of radial failure.

EXPERIMENTAL

Preparation of Tablets. Lubricants used were: hydrogenated vegetable oil[1], magnesium stearate NF, polyethylene glycol 4000 NF, stearic acid NF, and talc USP. Each lubricant was passed through a 60-mesh sieve immediately before mixing for 20 minutes in a twin shell blender with a 60/80-mesh sieve fraction of microcrystalline cellulose[2]. An appropriate weight of the blend was compressed at 454 kg of force for 5 seconds by means of 1.275 cm flat-faced punches and die fitted to a hydraulic press[3].

Measurement of Radial Tensile Strength and Work of Failure. The thickness of 10 tablets was measured using a micrometer. The maximum tensile failure force F_σ was measured by a dimetrial compression test using a tensiometer[4] modified for compression by the use of a compression device used for calibration of the mercury manometer of the tensiometer (3). The tablets were strained at the rate of 0.229 cm/min. The maximum tensile failure force F_σ of 10 tablets was determined, and the average was used to calculate the radial tensile strength σ_x by the relationship

[1]Lubritab, Edward Mendell Co.

[2]Avicel PH 102, FMC Corp.

[3]Carver press, model C, Fred Carver Inc.

[4]Hounsfield Tensometer, type W, Tensometer Ltd.

$$\sigma_x = \frac{2F_\sigma}{\pi D t} \text{ kg/cm}^2 \qquad \text{(Eq. 1)}$$

where D is the diameter (1.275 cm) and t is the thickness of the tablet (4).

The spring beam is that part of the tensiometer[4] through which the force is amplified and measured by the mercury manometer. The calibration by the manufacturer with its set of spring beams is such that a linear response between load beams is guaranteed. A force-displacement profile is linear for a brittle material and is nonlinear for a plastic material (microcrystalline cellulose). The maximum of the curve is the fracture force. The integral of the applied force F with respect to the deformation x may be termed the work of failure W_f

$$W_f = \int F \, dx \qquad \text{(Eq. 2)}$$

The linear response of brittle materials gives rise to a force-displacement profile in the shape of a right triangle, and by measuring the length of the base and height, and area can be calculated. For nonlinear force-displacement curves the areas under the curves were measured by planimetry.

Measurement of Axial Tensile Strength and Work of Failure. A tablet was aligned and fixed by a cyanoacrylate resin adhesive to machined heads of two bolts. By means of a pair of adapters the bolt-tablet-bolt assemblage was fitted horizontally into the tensiometer. The tensiometer allowed the recording of the stress component against the extension proportional to the distance moved by the crosshead beam as magnified and recorded on the drum chart paper. The maximum force of *axial tensile failure of 10 tablets was determined, and the average* was used to calculate the axial tensile strength σ_z by the relationship (5).

$$\sigma_z = \frac{4F_\sigma}{D^2} \text{ kg/cm}^2 \qquad \text{(Eq. 3)}$$

The axial work of failure was determined by integration of applied force with respect to platten displacement as recorded on the chart paper.

RESULTS AND DISCUSSION

The anisotropy of pharmaceutical tablets has been substantiated and studied in various regions of the tablet in terms of difference in density (6), fracture resistance (7), hardness (8), viscoelastic behavior (9) and tensile strength (10). The axial tensile strength has been report to be less than the radial tensile strength, and the ratio σ_z/σ_x has been suggested as an index of capping or resistance to failure. Using microcrystalline cellulose[2] as a model directly compressible material, tablets were compressed at 454 kg of force from pure microcrystalline cellulose and from blends containing various concentrations of the following lubricants: hydrogenated vegetable oil[1], polyethylene 4000, stearic acid and talc. For each of the tablets the radial tensile strength was greater than the axial tensile strength.

In Figure 1 the work of radial failure is plotted against radial tensile strength of the tablets. Similarly in Figure 2 the work of axial failure is plotted against axial tensile strength. It can be seen that considerably less work need be done to cause failure in the axial direction. It is recognized that tablets usually fail or cap in the axial direction, which has weaker bonding and strength than in the radial direction. Thus, when the work of axial failure is much less than the work of radial failure it would be anticipated that the tablet would have insufficient mechanical strength to withstand processing, handling and shipment.

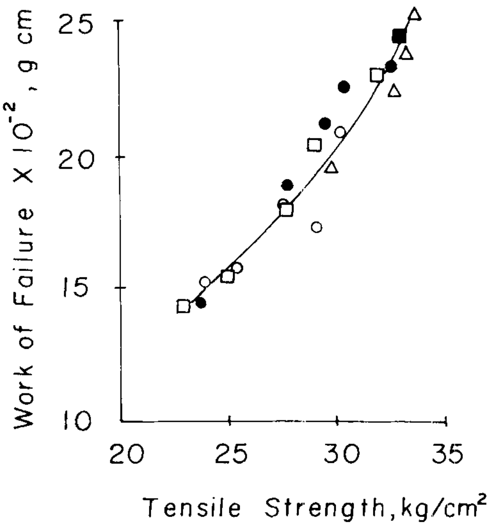

FIGURE 1.

Relationship of work of failure to radial tensile strength of micro-crytalline cellulose tablets containing various lubricants. Key: ○, polyethylene glycol 4000; △, talc; ●, hydrogenated vegetable oil; and, □, stearic acid.

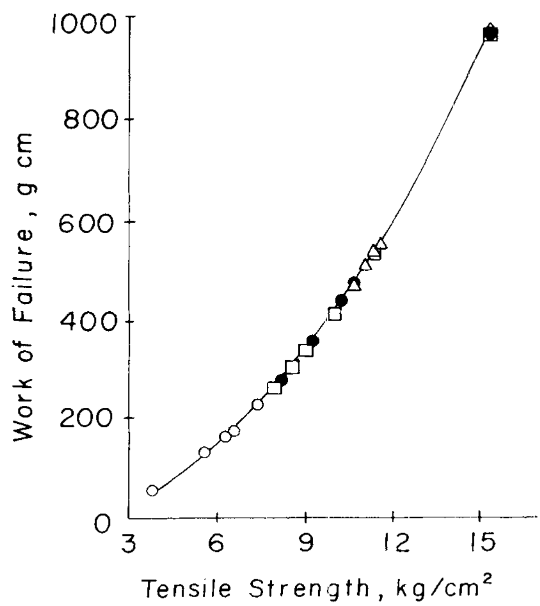

FIGURE 2.

Relationship of work of failure to axial tensile strength of micro-crystalline cellulose tablets containing various lubricants. Key: ○, polyethylene glycol 4000; △, talc; ●, hydrogenated vegetable oil; and, □, stearic acid.

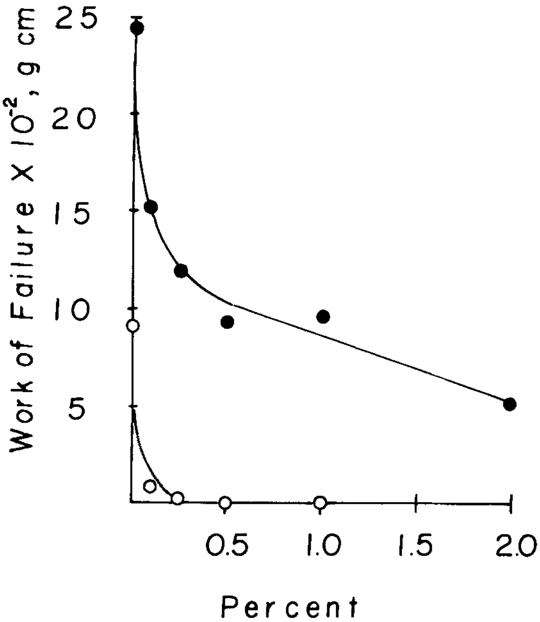

FIGURE 3.
The influence of concentration of magnesium stearate on the work of failure of microcrystalline cellulose tablets compressed at 454 kg. Key: ○ , axial; and ● , radial.

In general a solid lubricant decreases the strength of a tablet (11). A solid lubricant interferes with bonding by acting as a physical barrier between the particles for materials that undergo plastic deformation (12). As microcrystalline cellulose is a plastic material (13), it would be anticipated that a lubricant would reduce tablet strength and less work would be required to cause failure.

As shown in Figure 3 the lubricant reduces the work of axial failure from 856 g cm for tablets of pure microcrystalline cellulose to 28 g cm for tablets containing 0.25% magnesium stearate. Obviously, with so small a value of the work of failure such a tablet is unsatisfactory for handling and shipment. The incorporation of 0.25 and 2.0% magnesium stearate reduced the work of radial failure to 48 and 20% that of the pure microcrystalline cellulose tablet.

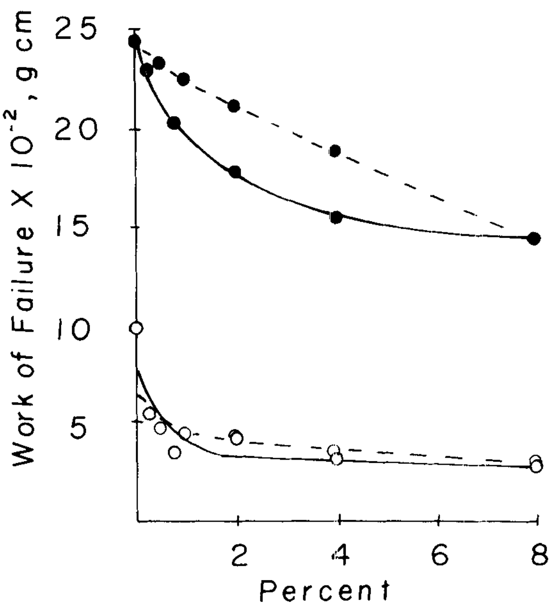

FIGURE 4.

The influence of concentration of stearic acid and hydrogenated vegetable oil on the work of failure of microcrystalline cellulose tablets compressed 454 kg. Key: ——, stearic acid; ---, hydrogenated vegetable oil; ○, axial; and, ●, radial.

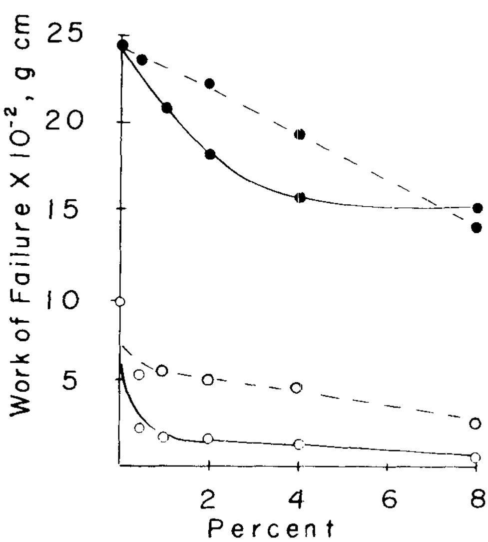

FIGURE 5.

The influence of concentration of polyethylene glycol 4000 and talc on the work of failure of microcrystalline cellulose tablets compressed at 454 kg. Key: ——, polyethylene glycol 4000; ---, talc; ○, axial; and, ●, radial.

The influence of concentration of stearic acid and hydrogenated vegetable oil[1] on the work of failure of microcrystalline cellulose tablets is shown in Figure 4. Again the work of failure is decreased as the concentration of lubricant is increased, but the greater degree of change is the lowering of the work of axial failure. For example with 2% hydrogenated vegetable oil the work of radial failure is lowered 4%, but the work of axial failure is lowered 57%.

The influence of concentration of polyethylene glycol 4000 and talc on the work of failure of microcrystalline cellulose is shown in Figure 5. All of the lubricants studied produced tablets that had a low value of the work of axial failure.

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