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Mechanical property anisotropy of pharmaceutical excipient compacts

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Abstract

The mechanical property anisotropy of compacts made from six commercially available pharmaceutical excipient powders was evaluated. Uni-axially compressed cubic compacts of each excipient were subjected to pendulum impact testing and transverse tensile testing in several orientations. The pendulum impact test was used to measure the dynamic indentation hardness of each compact face (side, top, and bottom). Transverse tensile testing was utilized to determine the compact axial and radial tensile strength values. The indentation hardness (top > bottom > side) and tensile strength tests (radial > axial) revealed mechanical property anisotropy in all the compacts. The extent of mechanical property anisotropy was quantified by using dimensionless ratios and was found to be significantly different for each material. In general, compacts with a higher degree of compact mechanical anisotropy also exhibited a higher brittle fracture index (BFI). This suggests that the macroscopic flaws intentionally made in the compact for the BFI measurement were similar to the flaws induced in highly anisotropic materials during uni-axial compaction. These results are consistent with the practical observation that brittle materials are more likely to exhibit failure in a plane normal to the compaction axis, i.e. experience tablet capping and lamination phenomena.
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1. Introduction

Pharmaceutical tablets are typically formed by uni-axial compression of a powder into a coherent compact using an upper punch, a lower punch, and a die. Compacts that are formed in this manner have been reported to exhibit different mechanical property values, e.g. tensile strength, when measured in different orientations and therefore are mechanically anisotropic (Nystrom et al., 1978; Alderborn and Nystrom, 1984; Newton et al., 1993; Malamataris et al., 1995; Moe and Rippie, 1997; Edge et al., 2001). It has been suggested that mechanical property anisotropy in compacts is important because it contributes to tablet manufacturing failures such as capping and lamination (Nystrom et al., 1978). Therefore, the measurement of this powder compact property is essential to the improved prediction of tableting performance.

Recent research has proposed several possible explanations for the observed compact mechanical property anisotropy. On the microscopic level, fracture toughness anisotropy has been observed in single crystals of acetaminophen and sucrose using indentation hardness tests (Duncan-Hewitt and Weatherly, 1989; Duncan-Hewitt et al., 1994). The directionally preferential crack propagation was attributed to single crystal slip plane biases. In bulk powder compression, these types of biases may enable the formation of cleavage planes perpendicular to the direction of compression causing preferential compact failure, i.e. lamination or capping (Sun and Grant, 2001). From a bulk powder perspective, it has been suggested that irregular or even preferential packing of non-spherical particles could facilitate compact structure directionality (Li and Puri, 1996). If the particles were to align during die filling, it could contribute to the compact's mechanical property anisotropy. Likewise, if the particles were to pack differently at the points of contact with the punches and die, this may induce a mechanical property anisotropy as well.

Mechanical property anisotropy is likely to have a significant effect on pharmaceutical tableting performance, and thus an accurate quantification of this phenomenon is highly desirable. To date, a combination of test methods has been employed for anisotropic compact mechanical property evaluations, most of which utilize complex experimental setups and require direct

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comparison of the mechanical properties values calculated from different analytical solutions (Nystrom et al., 1978; Jarosz and Parrott, 1982; Alderborn and Nystrom, 1984; Newton et al., 1993; Malamataris et al., 1995; Moe and Rippie, 1997; Edge et al., 2001). There is a need for a simplified method of assessing the anisotropic potential of both robust and fragile materials. The objective of this work was to develop a unified test method for measuring anisotropy in uni-axially compacted pharmaceutical compacts using a geometrically isotropic body and to investigate the degree of mechanical property anisotropy in these compacts in an attempt to provide improved a priori assessments of tableting behavior.

2. Materials

Six commercially available pharmaceutical excipient powders were evaluated as received from the vendors: α-lactose monohydrate (Regular 310, Foremost, Rothschild, WI), spray dried lactose (Fast Flo, Foremost, Rothschild, WI), microcrystalline cellulose (Avicel PH102, FMC, Newark, DE), dibasic calcium phosphate anhydrous (A-Tab, Rhodia, Chicago, IL), hydroxypropyl cellulose (Klucel EXF, Hercules, Hopewell, VA), and aspartame (Spectrum, Gardena, CA). These powders were selected because they are commonly used in immediate release tablet formulations (Rowe et al., 2003). The data presented in this work are specific to these powder lots, which were representative of lots previously received from the vendors. The powders were stored at environmentally controlled laboratory conditions of 20 ± 2 °C and 40 ± 10% relative humidity.

2.1. Methods

2.1.1. Compact preparation

Cubic compacts (∼1 g measuring 9.5 mm × 9.5 mm × 9.5 mm) were formed by uni-axial compression (∼1 mm/s compression speed) using a custom built press that permitted gradual triaxial decompression of the samples. Prior to compression, the punch and die surfaces were sparingly lubricated with magnesium stearate suspended in methanol (5%, w/v). In this setup as shown in Fig. 1, the bottom punch was stationary while the top punch was moving (similar to an eccentric tablet press). The compression dwell time was 1.5 min and triaxial decompression time was 2 min to enable the formation of high quality compacts. Each powder was compressed to a target solid fraction of 0.85 when possible, which is typical of pharmaceutical tablets (Hancock et al., 2003). The dibasic calcium phosphate sample was compressed to a lower solid fraction (0.64) due to the unique properties of this material. Solid fraction is defined as the proportion of solid in the compact, i.e. 1–porosity. The cubic test samples could be evaluated in different orientations using the same testing equipment and less than 10 g of each material was required for this evaluation.

2.1.2. Mechanical property characterization

The tensile strength of the compacted samples was determined by transverse compression with a custom built tensile tester (Hiestand and Smith, 1984). Tensile failure was observed for all the cubic compacts when compressed between flat-faced platens at a speed of ∼0.01 mm/s. A small hole (0.5 mm diameter) was made through and parallel to the breaking plane of the compacts to act as a stress concentrator. This measurement was used to determine the compromised tensile strength in the axial and radial direction (Fig. 1). These measurements were performed in triplicate, both parallel (axial strength) and perpendicular (radial strength) to the compression axis.

Dynamic indentation hardness determinations were performed using a pendulum impact device (∼1000 mm/s impact speed) (Hiestand and Smith, 1984). The spherical indentor was of 12.7 mm diameter and 42 g mass, and the pendulum length was 923 mm with a release angle of 20°. The compact indentations were measured using a white light interferometer (Zygo Corporation, Middlefield, CT) and the dent diameter and pendulum initial and rebound heights were used to calculate the dynamic indentation hardness of the compacts (Hiestand and Smith, 1984). Indentation testing was performed on the top, bottom, and side surfaces of the same compact (see Fig. 1) to minimize compact-to-compact variations and solid fraction effects. Preliminary experiments showed that the values of indentation hardness did not measurably change when tested on "fresh" or "previously dented" compacts (data not shown).

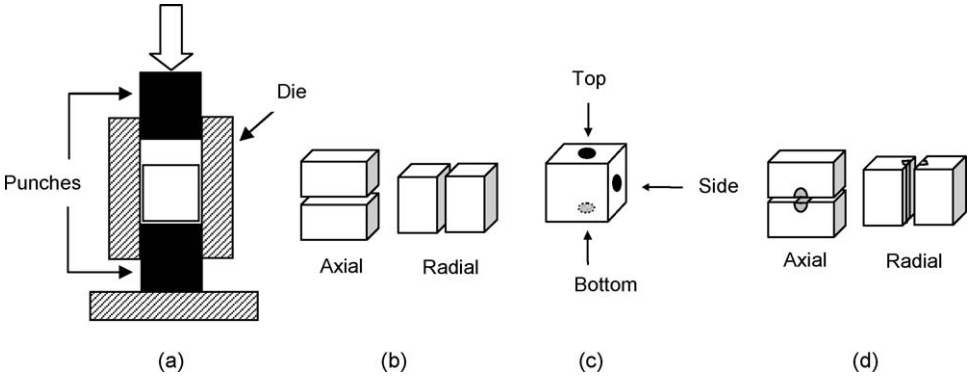

Fig. 1. Schematics of the: (a) compaction apparatus, (b) tensile break planes, (c) indentation surfaces, and (d) tensile strength planes with a controlled defect.

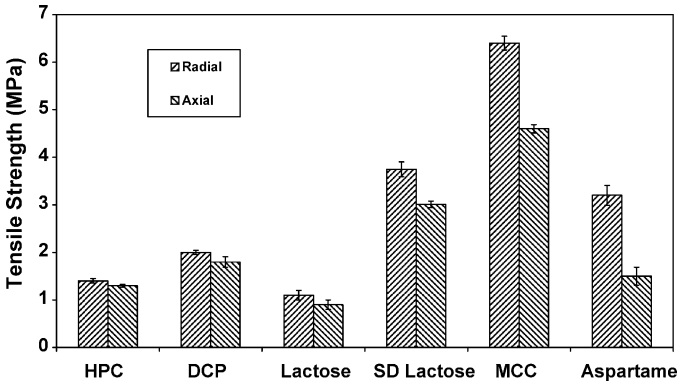

Fig. 2. Tensile strength anisotropy values for different compact planes.

3. Results and discussion

3.1. Tensile strength anisotropy

Measurable differences were detected among the radial tensile strength values of the powder compacts compressed to 0.85 solid fraction: MCC > SD lactose > aspartame > HPC > lactose. A similar trend was observed for the axial tensile strength values as shown in Fig. 2. The dibasic calcium phosphate compacts compressed to a solid fraction of 0.64 exhibited a "moderate" tensile strength compared to the other excipients (Mullarney and Hancock, 2004) and would be expected to exhibit much higher strength at 0.85 solid fraction (Hiestand, 2002).

The axial tensile strength was constantly lower than the radial tensile strength for all the excipients studied. This is consistent with previously reported studies using acetylsalicylic acid blends, paracetamol granulations, microcrystalline cellulose, dibasic calcium phosphate, and lactose powders (Nystrom et al., 1978; Jarosz and Parrott, 1982; Alderborn and Nystrom, 1984; Edge et al., 2001). It has been proposed that these differences in axial and radial tensile strength values could be caused by a number of factors including: uneven die or tooling friction, crystal slip plane biases (Duncan-Hewitt and Weatherly, 1989; Duncan-Hewitt et al., 1994; Sun and Grant, 2001), preferred particle orientation during die filling or compaction (Li and Puri, 1996), and/or non-uniform axial and radial compact strain recovery following compaction (Aulton et al., 1973).

Although the data presented here do not explain the mechanism for the differences in axial and radial tensile strength, the presence of this mechanical anisotropy is important for tablet manufacturing. In-process tablet crushing strength determinations traditionally measure the radial crushing strength of the compact even though tablet failure during handling and use is almost always in the axial direction, e.g. lamination and capping. The measurement of axial tensile strength may be a much better indicator of tablet robustness because of this, and also because it clearly describes the weakest plane of uni-axially compressed compacts. The unified test method used in this work is desirable for these measurements because it enables a direct comparison of the axial and radial tensile strength values.

The degree of tensile strength anisotropy (α) was quantified for each material by taking the ratio of the axial to radial tensile strength. As α values approach unity, the compact is considered to be more isotropic.

$$\alpha = \frac{\sigma_T\,(\text{axial})}{\sigma_T\,(\text{radial})}$$

For the compacts tested, the mean values of α ranged between 0.47 and 0.93 as shown in Table 1. The most anisotropic material was aspartame and least anisotropic material was hydroxypropyl cellulose.

The tensile strength data reported here are consistent with anisotropic parameters derived from viscoelastic analysis by Moe and Rippie (1997), where hydroxypropyl cellulose was reported to be relatively isotropic compared to other common excipients and crystalline drugs. The dibasic calcium phosphate sample showed relatively low tensile strength anisotropy. Since this sample was compressed to a relatively low solid fraction (0.64), its degree of anisotropy could be different at a solid fraction of 0.85. The effect of solid fraction on anisotropy requires further investigation, but it is conceivable that the relative degree of anisotropy could increase because higher compression forces typically induce capping and lamination phenomenon.

Both lactose samples exhibited moderate tensile strength anisotropy relative to the other materials tested, suggesting that these materials could exhibit a tendency for tablet lamination. Critical stress intensity factor values reported in the literature support these findings, where α-lactose monohydrate compacts have moderate fracture toughness (0.35 MPa $m^{0.5}$) when compared to good tableting materials such as microcrys-

Table 1
Compact anisotropic values and brittle fracture indices (mean and standard deviation)

	Tensile strength anisotropy, α	Indentation hardness anisotropy, β	Brittle fracture index, BFI	
			Radial	Axial
Hydroxypropyl cellulose	0.93 (0.02)	0.90 (0.05)	−0.02 (<0.01)	0.01 (0.01)
Dibasic calcium phosphate anhydrous	0.90 (0.03)	0.81 (0.02)	0.04 (0.01)	0.05 (0.02)
α-lactose monohydrate	0.82 (0.07)	0.69 (0.02)	[a]	[a]
Spray dried lactose	0.80 (0.02)	0.81 (0.03)	0.41 (0.03)	0.56 (0.04)
Microcrystalline cellulose	0.72 (0.01)	1.13 (0.22)	0.05 (0.02)	0.33 (0.02)
Aspartame	0.47 (0.04)	0.65 (0.06)	0.79 (0.06)	0.50 (0.11)

[a] Note: Compacts with holes consistently broke during preparation.

talline cellulose (0.76 MPa $m^{0.5}$) and poor tableting materials such as acetaminophen (0.11 MPa $m^{0.5}$) (Rowe and Roberts, 1996). In a tablet formulation, a material with a low α value, such as aspartame, should probably be used sparingly to reduce the likelihood of compact lamination during decompression.

The microcrystalline cellulose compact exhibited an α value of 0.72. This is higher than the 0.45 and 0.47 α values reported by Edge et al. (2001) and Jarosz and Parrott (1982) for microcrystalline cellulose. Differences between these data may be due to several factors, e.g. material moisture content, compression conditions, compact solid fraction, and measurement technique. For example, Jarosz and Parrott (1982) used different testing orientations and analytical equations to calculate the radial and axial tensile strength of cylindrical compacts. Nonetheless, all datasets suggest significant tensile strength anisotropy in microcrystalline cellulose compacts. The possible implications of this result will be discussed later.

3.1.1. Indentation hardness anisotropy

The pendulum impact test on the top surface of each compact, as shown in Fig. 1, was used to rank the dynamic indentation hardness (H_0) of materials compressed to a solid fraction of 0.85: spray dried lactose > aspartame ≈ microcrystalline cellulose > lactose monohydrate > hydroxypropyl cellulose. The spray dried lactose compacts exhibited relatively high dynamic indentation hardness (648 MPa), while the hydroxypropyl cellulose compacts exhibited relatively low dynamic indentation hardness (73 MPa) when compared to other common excipients (Mullarney et al., 2003). Compacts with lower indentation hardness at the same solid fraction are more ductile and are expected to form larger interparticulate surfaces for bonding to occur upon compression. The dibasic calcium phosphate powder could only be compressed to a solid fraction of 0.64 under these compression conditions due to its high dynamic indentation hardness (335 MPa). This is not surprising since the yield stress of dibasic calcium phosphate is nearly 10× that of microcrystalline cellulose (Rowe and Roberts, 1996).

The top, bottom, and side face indentation hardness values revealed that the surfaces that were in contact with the punch faces (top and bottom) were generally harder than the surfaces in contact with the die (side) (see Fig. 3). It is not surprising that the sides exhibit a different indentation hardness because uni-axially compressed compacts possess a discernable porosity distribution in their bulk structure (Train, 1957). It has been reported that the surface in contact with the moving punch is slightly less ductile than the surface in contact with the stationary punch (Aulton, 1981). This has been explained through models and experiments where in single sided compaction (lower punch fixed), there is a solid fraction decrease from the top to the bottom in powder compacts (Zhou et al., 2002; Michrafy et al., 2003) and an exponential decay of punch force from top to bottom (Unckel, 1945). However, even though the same test method was used for the indentation test, it was not able to effectively discriminate between the top and bottom surface hardnesses because of its insensitivity to small differences (±8%) even in replicate dynamic indentation hardness determinations (Mullarney and Hancock, 2004).

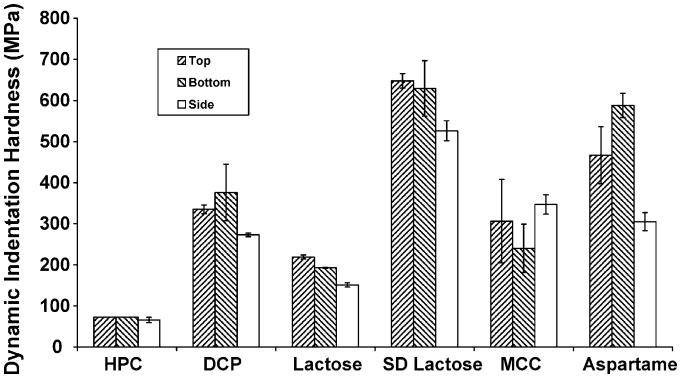

Fig. 3. Dynamic indentation hardness values for different compact surfaces.

The degree of indentation hardness anisotropy (β) was estimated by using the ratio of the side and top indention hardness values:

$$\beta = \frac{H_0\,(\text{side})}{H_0\,(\text{top})}$$

As β values approach unity, the compact is considered to be more isotropic. As shown in Table 1, the mean values of β ranged from 0.65 to 1.13 and the relative degree of indentation hardness anisotropy was aspartame ≈ lactose > SD lactose ≈ DCP > HPC ≈ MCC. As observed for the tensile strength anisotropy data, hydroxypropyl cellulose was highly isotropic and aspartame was highly anisotropic, however there was no quantitative correlation between α and β. The observed differences in indentation hardness on the punch (top) and die (side) surfaces are likely due to the non-uniform stress distribution induced during uni-axial compaction (Train, 1957; Eiliazadeh et al., 2003). Presumably materials such as hydroxypropyl cellulose experience a more even stress distribution during compact formation, and the converse is true for powders such as aspartame.

3.1.2. Correlation between the anisotropic indices and the brittle fracture index

Hiestand proposed that the brittle fracture index (BFI) is inversely related to a material's ability to undergo localized stress relief through plastic deformation. Such stress relief is thought to prevent capping and lamination occurrences in a tablet (Hiestand and Smith, 1984). The BFI is calculated from the tensile strength of compacts with (σ_{T0}) and without (σ_T), a controlled defect running through the failure plane.

$$\text{BFI} = 0.5\left(\frac{\sigma_T}{\sigma_{T0}} - 1\right)$$

Since the BFI describes the "strongest" and "weakest" states of the compact in a single orientation, it is plausible that the BFI relates to the anisotropic indices α and β, which also could be used to describe the strongest and weakest aspects of a compact.

The anisotropic indices, α and β, were compared with both the axial and radial BFI values for each material as shown in Table 1. For materials that were extremely brittle, such as

aspartame (radial/axial BFI = 0.79/0.50), both the α (0.47) and β (0.65) values were generally low. The converse was also true for low brittleness materials such as hydroxypropyl cellulose (radial/axial BFI = 0.0/0.0), where the α (0.93) and β (0.90) values were generally high. The spray dried lactose sample exhibited moderate mechanical anisotropy and somewhat high brittleness (radial/axial BFI = 0.41/0.56). These data suggest that compact brittleness may be related to and generally trends with compact anisotropy. Therefore much like brittle materials, materials that form highly anisotropic compacts may also be undesirable in tablet formulations.

The α-lactose monohydrate samples had α and β values of 0.82 and 0.69, suggesting the compacts were moderately anisotropic. This is an important observation when one also considers the low tensile strength of this material relative to other pharmaceutical excipient compacts (Mullarney and Hancock, 2004). The moderate degree of anisotropy (and presumably moderate brittleness) *coupled* with the low tensile strength suggests that this material will form tablets with a high tendency for lamination. This was confirmed by the observation that it was impossible to make compacts of this material with a controlled defect. It should also be noted that when materials with these combined properties are encountered, the test methods used in this work may be very useful for determining lamination tendency because they do not require compacts to be made with a controlled defect.

Somewhat surprisingly, the microcrystalline sample exhibited a relatively high degree of anisotropy. This seemed contradictory to practical manufacturing experience where this material typically creates highly robust tablets. This observation can also be explained by reference to the tensile strength of this material. It is likely that the very high tensile strength of microcrystalline cellulose (6.4 MPa) acts to compensate for its inherent anisotropy and thus enables robust compact formation. Therefore, despite its relatively high degree of anisotropy, this material normally exhibits a low tendency for capping by maintaining very strong interparticulate bonds. This further supports Hiestand's original work (Hiestand, 2002), where he used multiple compact properties to fully describe a material's potential for tableting performance.

The α and β anisotropic indices for dibasic calcium phosphate were 0.90 and 0.81, respectively. These are generally high compared to the other materials tested and suggest a low to moderate degree of compact anisotropy. These samples also exhibited low BFI values ($\sim$0.05), which support the trending of compact brittleness with anisotropy. Because the dibasic calcium phosphate samples were compressed to a much lower solid fraction than the other samples, a direct comparison was not possible. Related work by Roberts and Rowe (1986) showed that for inorganic materials such as heavy magnesium carbonate, the BFI increases ($\sim$0.2 to $\sim$0.45) with solid fraction ($\sim$0.50 to $\sim$0.65) at slow compaction speed. They hypothesized that the "shapes and orientation of the (interparticulate) pores formed may vary" as solid fraction is increased. This work suggests that the effect of solid fraction on compact anisotropy is clearly an area for future investigation since it is a fundamental contributor to the properties of pharmaceutical tablets.

4. Conclusions

As significant degree of anisotropy has been demonstrated in powder compacts of common pharmaceutical excipients made by uni-axial compression using the techniques described in this study. In general, materials with higher anisotropy (anisotropic indices, α and β) also had a higher brittle fracture index suggesting that they are less likely to relieve interparticulate stresses through plastic deformation. The methods used provide insight into the performance of common pharmaceutical materials and enable a more intuitive method for determining their likely capping and lamination tendencies. This unified testing methodology for determining compact anisotropy is attractive for the formulation scientist because it is simple, broadly applicable, and requires a small amount of material.

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