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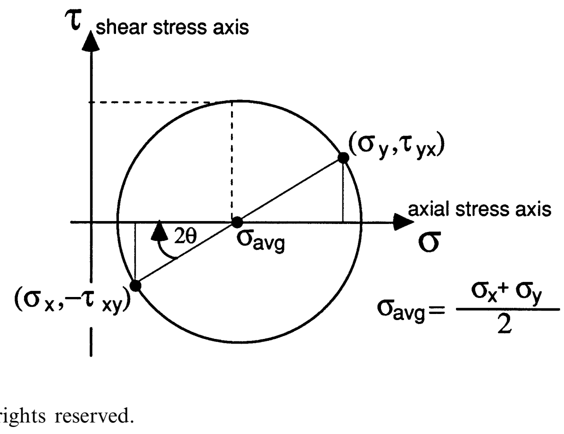
We are in complete agreement with the assessment by Newton and Podczeck of the complex mechanisms arising from the compressive stress imparted to a powder bed during uniaxial densification. As is well appreciated in pharmaceutics related invesigations, the densification or volume reduction of a powder bed under such a stress does not necessarily lead to the consolidation of the powder into a durable compact. It is precisely this duality that challenges the formulating scientist when attempting to utilize descriptive parameters to characterize the strength of compacted particulate solids as a result of tableting. The pharmaceutical literature has borrowed extensively from other disciplines in attempting to utilize various tests in the strength assessment of compacts formed with pharmaceutical ingredients, the most common being the Brazilian test of diametral or radial crushing (Barcelos and Carneiro, 1953). However as well, other tests often are used for similar strength measurements of compacts including bending strength (David and Augsberger, 1974) and axial strength (Nyström et al., 1978), the latter presented in the cited paper (Vachon and Chulia, 1999). Tensile strength, necessarily subscripted by the method of determination, is routinely ascertained from these measurements without explicit knowledge of the stress distribution within the samples.

The mechanical behaviour of a tablet depends not only on the intrinsic strength of the interparticle bonds, but also on the deformation characteristics of the solid and the stress-strain behaviour of the bonds. It is the sum of such effects that determine whether a compact possesses a high or low resistance to mechanical damage as assessed by a parameter such as the isotropy ratio (Müller and Steffens, 1976), indentation hardness (Hiestand and Smith, 1984; Doelker et al., 1989), work of failure (Rees and Rue, 1978; Jarosz and Parrott, 1982) and indeed, the resistance to rupture (Reyss-Brion et al., 1985) utilized in our paper. Typically, force–displacement profiles of tablets under compressive load are not linear. The extent of curvature is an indication of tablet deformation occurring. Since compacts of materials are inherently anisotropic, the calculation of tensile strength is best viewed as a surrogate estimate of compact strength. In order to account for both the axial stress (σ) as well as the shear stress (τ) experienced by a cylindrical compact (i.e a tablet) subjected to compressive load, the isolation of the contributing stresses is necessary. A useful way of expressing and visualizing the plane stresses in this particular loaded structural element is the method known as Mohr's Circle (Costet and Sanglerat, 1975) represented in the following figure for the general case:



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where the Mohr's Circle angle, 2θ, is twice the angle in real space and σ_{avg} is equal to $(\sigma_x + \sigma_y)/2$. When there is only a single normal component of stress, as in the case of uniaxial stress, σ_x is set at zero and σ_y is the applied uniaxial stress resulting in rupture of the compact. Under these conditions, it is evident that σ_{avg} is 1/2 of the applied uniaxial stress σ_y, that τ_{max} (i.e. the radius of the circle) is also 1/2 of the applied uniaxial stress σ_y and that τ_{max} occurs at 90° in the material from the orientation of the uniaxial stress. According to this theoretical basis, we have elected to define τ_{max} as the resistance to rupture, R, in order to remove any potential confusion with tensile stress designations.

Although not categorically stated, the dimensions of the consolidating cell outlined in the experimental section, on the one hand, and the maximum displacement of the upper platen during application of compaction load, noted in Table 1, on the other hand, both prove that the diameter of the resulting compact in no case exceeded the value of the compact height.

No single procedure can be purported to be superior a priori since in all cases, the tensile strength must be subscripted by the test method used to obtain it because of inherent assumptions associated with carrying out the measurement. Indeed, axial strength assessment of compacts is particularly suited to facilitate the identification of capping and lamination tendencies since the compact breaks in a plane normal to its axis (Alderborn and Nyström, 1984). In the investigation cited, (Vachon and Chulia, 1999), some compacts did exhibit failure in a 45° plane to the axis of applied stress, consistent with the Mohr's Circle calculations.

While our goal is to be able to predict and control the behaviour of a specific formulation in an arbitrary compaction procedure, the list of intrinsic properties of the materials and extrinsic factors at play in such a process preclude the definition of a comprehensive model. Although relationships developed in the study of compact behaviour may be tenuous in the least, our results indicate the potential utility of this approach as a diagnostic tool during material compaction evaluation studies.

References

Alderborn, G., Nyström, C., 1984. Radial and axial tensile strength and strength variability of paracetamol tablets. Acta Pharm. Suec. 21, 1–8.

Barcelos, F.L.L.B., Carneiro, A., 1953. Résistance à la traction des bétons. RILEM Bull. No. 13, 97–123.

Costet, J., Sanglerat, G., 1975. Cours pratique de mécanique des sols plasticite et calcul des tassements. Dunod Technique, Paris.

David, S.T., Augsberger, L.L., 1974. Flexure test for determination of tablet tensile strength. J. Pharm. Sci. 63, 933–936.

Doelker, E., Mordier, D., Kopp, S., 1989. Relevance of various mechanical strength measurements of pharmaceutical compressed tablets. In: Biarez, J., Courvés, R. (Eds.), Powder and Grains. Balkema, Rotterdam, pp. 411–416.

Hiestand, E.N., Smith, D.P., 1984. Indices of tableting performance. Powder Technol. 38, 145–159.

Jarosz, P.J., Parrott, E.L., 1982. Effect of tablet lubricants on axial and radial work of failure. Drug Dev. Ind. Pharm. 8, 445–453.

Müller, B.W., Steffens, K.-J., List, P.H., 1976. Untersuchungen zur exakten bestimmung der bruchfestigkeit von tabletten. Acta Pharm. Technol. 22, 91–108.

Nyström, C., Malmqvist, K., Mazur, J., Alex, W., Hblzer, A.W., 1978. Measurement of axial and radial tensile strength of tablets and their relation to capping. Acta Pharm. Suec. 15, 226–232.

Rees, J.E., Rue, P.J., 1978. Work to cause failure of tablets in diametral compression. Drug Dev. Ind. Pharm. 4, 131–156.

Reyss-Brion, R., Chulia, D., Vérain, A., 1985. Etude de quelques excipients de compression directe: caractérisation technologique. STP Pharma 1, 632–637.

Vachon, M.G., Chulia, D., 1999. The use of energy indices in estimating powder compaction functionality of mixtures in pharmaceutical tableting. Int. J. Pharm. 177, 183–200.

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