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The instrumentation of a Zanasi LZ/64 capsule filling machine

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The dosator system of a Zanasi LZ/64 capsule filling machine was modified and strain gauges were fitted. These were used to measure the forces on the powder being filled during compaction and ejection. The patterns of those forces produced were shown to differ between different materials and between lubricated and unlubricated materials. Tentative reasons for the observed differences have been suggested.

The speed of capsule filling has lagged far behind that of its main alternative as a dosage form, the compressed tablet. There are signs, however, that the gap is beginning to close and machines capable of filling between 100 000 and 150 000 capsules per hour have become available. To fill capsules at this speed, some leading equipment manufacturers have developed the technique of compressing the powder to form a plug or pellet, which is then inserted into the capsule shell. This process is similar to tablet making and therefore it seems logical to apply some of the techniques used to study the tablet compaction process (*cf.* Higuchi, Nelson & Busse, 1954; Higuchi, Busse & others, 1956; Long, 1960; Leigh, Carless & Burt, 1967; Haussen, Fuhrer & Schafer, 1970) to this method of filling capsules. Our object is to describe the methods used to instrument a Zanasi LZ/64 capsule filling machine, and the techniques used to record and measure the forces produced during the capsule-filling process.

The principle of this type of machine is that a tubular nozzle dips into a powder bed of constant depth.

The capsule fill weight depends on: (*a*) The position of the dosator in the dosator nozzle, distance x in Fig. 1. (*b*) The powder depth in the dosator hopper. (*c*) The bulk density of the material in the dosator hopper. (*d*) The machine filling speed. During plug formation the distance x is always less than the depth of powder in the hopper. To eject the powder plug into the capsule body, the piston is moved to the end of the dosator nozzle, pushing the plug before it, after which the spring returns it to its original position. In our studies, the forces measured were those which were exerted by the powder along the axis of the dosator piston. These forces act on the end of the piston during formation, carry over, and ejection of the powder plug.

The small value of forces exerted during capsule filling made measurement difficult. On a tablet machine the punch forces during compression are typically 3×10^4 N, whereas in the present work the forces involved never exceeded 400 N and more typically were 20–30 N. To measure force of this order, a large degree of amplification is necessary, with its attendant drift and signal to noise ratio problems.

Equipment

Four 120 ohm linear foil strain gauges, Philips type PR 9833K/01 SE, were used to measure these forces. Two active gauges and two passive gauges were used in each

of two arms of a Wheatstone bridge; the other two arms of the bridge were fixed resistors in the amplifier. The two active strain gauges were mounted on two flat surfaces ground onto opposite sides of the dosator piston (See Fig. 1). This configuration was used to increase the sensitivity of the system and to minimize the effect of any forces which may be generated by bending of the piston. It was demonstrated that when an uncompensated piston was subjected to a bending stress in a plane parallel to the sensitive axis of the gauge, a response of comparable magnitude to that produced by the forces measured was observed.

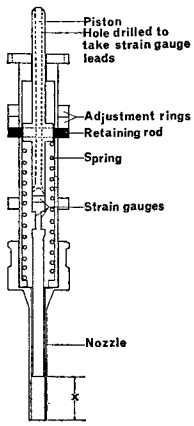

FIG. 1. Dosator assembly.

The leads from the strain gauges were led out through a hole drilled along the length of the dosator piston. To prevent the leads to the instrumented dosator from becoming twisted during operation, the machine was modified so that the dosator made one complete clockwise revolution on its axis for each anticlockwise revolution of the head (*a*) upon which it is mounted (See Fig. 2).

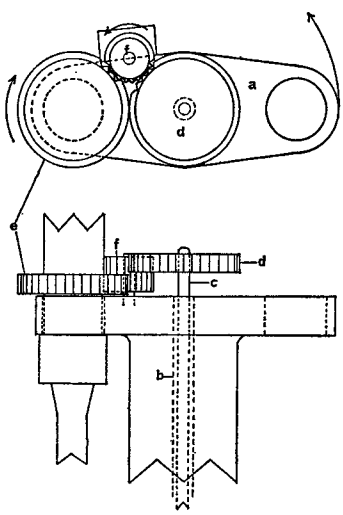

FIG. 2. Modifications to rotating dosator head.

The drive shaft to the rotating head was replaced by a stainless steel tube (*b*) through the centre of which passed a rod (*c*). Fixed on top of the rod was a nylon gear wheel (*d*) positioned just above the rotating head. This gear wheel was fixed so that it could not revolve. A second gear wheel, (*e*) of the same size as (*d*) was attached to the body of the instrumented dosator. This wheel was linked to (*d*) via a third smaller gear (*f*) to make the dosator rotate in the correct direction. A small amount was machined off the dosator carrier (*a*) so that the dosator body was free to rotate when the nozzle was fitted and tightened.

Signal processing was carried out by an S.E. Laboratories 4000 system. This consisted of a 5 V oscillator, operating at 3 kHz, to energize the strain gauges and a carrier amplifier/demodulator to measure the bridge unbalance. The output was recorded on a S.E. Laboratories ultraviolet recording oscillograph type 3008 fitted with a B450 galvonometer.

Calibration

The instrumented piston was calibrated using the loaded beam technique of Brook & Marshall (1968). Loading the piston with a force of 250 N gave a galvanometer beam deflection of 80 mm. Smaller forces were used to construct a calibration graph which was a straight line passing through the origin.

To evaluate the influence of bending movements during compression of the piston, it was also calibrated in tension by hanging weights from it. A straight line through the origin was obtained with tensile forces from 60 N through the origin to a compression force of 100 N, and this confirmed the adequacy of the flexion compensating strain gauge.

Methods

Experiments were made using size 00 capsules at a filling speed of 50 min^{-1}. The materials used were microcrystalline cellulose (Avicel pH 101, FMC Corporation), a modified corn starch (Sta-Rx 1500, A. E. Staley Manufacturing Co. (London) Ltd.) and two grades of lactose, 50 T and 80 mesh (Whey Products Ltd.). These materials were used alone and with the addition of 0·5% w/w magnesium stearate B.P. (Durham Chemicals Ltd.) as lubricant.

The machine was run for several revolutions, before fitting the dosator nozzle, to stabilize the powder level in the dosator hopper. With the lubricated materials several capsules were produced before taking recordings of pressure. With the unlubricated materials, recordings were made immediately after fitting the dosator to study the onset of binding. A recording was made with the machine running and the powder hopper removed, to ascertain the effects of machine movement on the oscillograph trace, Fig. 3 J. Bulk density measurements on unlubricated and lubricated materials were made according to BSS 1460:1967. Particle size analysis was by using a nest of sieves.

The properties of the materials examined are shown in Tables 1 and 2.

RESULTS

The traces are shown in Fig. 3, A–I. The second event marker on each trace shows when the powder plug is ejected into the capsule.

Fig. 3 C shows a general pattern of force, which is modified in its detail by the characteristics of the material in use. An initial compaction force is produced at a,

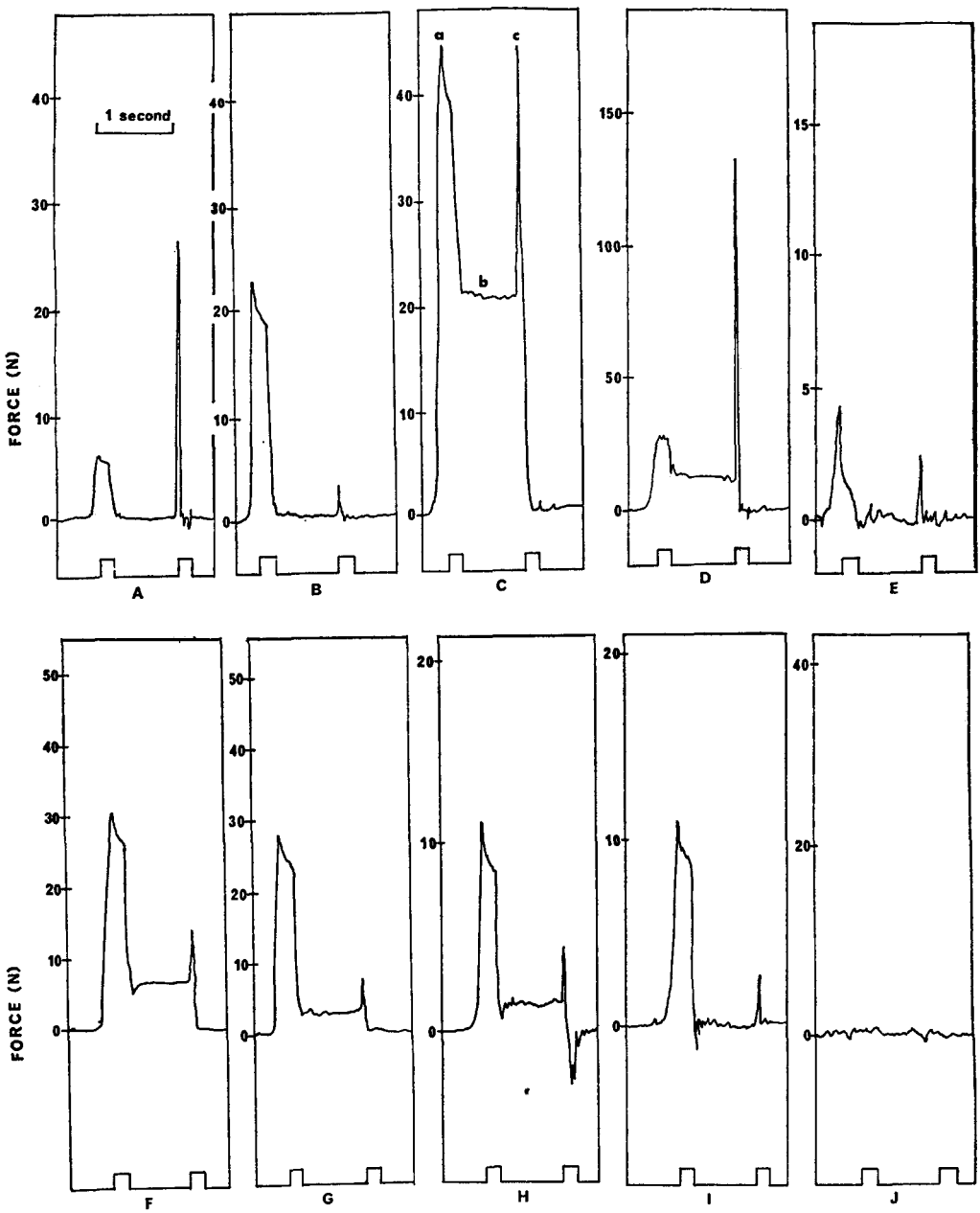

FIG. 3. A. Lactose 80 mesh., B. Lactose 80 mesh + 0·5 % magnesium stearate. C. Lactose 50T after 20 capsules. D. Lactose 50T after 50 capsules. E. Lactose 50T + 0·5% magnesium stearate. F. Avicel. G. Avicel + 0·5% magnesium stearate. H. Sta-Rx 1500. I. Sta-Rx 1500 + 0·5% magnesium stearate. J. Machine noise.

as the plug is formed, and is partially retained, b, during carry over of the plug to the capsule body. A second force is produced at c, as the powder plug is ejected into the capsule body. This second force, c, changes according to the extent of lubrication of the material. An examination of figures 3C and 3D shows the rapid build

Table 1. *Particle size distribution of powders used.*

Sieve	Lactose 80 mesh %	Lactose 50T %	Avicel pH 101 %	Sta-Rx 1500 %
On 60	0	0	0	1·2
On 100	3·8	18·3	1·5	6·0
On 150	12·6	38·0	6·5	11·7
On 200	14·8	20·0	12·4	14·6
On 350	30·3	18·5	33·4	22·6
Through 350	39·3	4·2	46·2	43·6

Table 2. *Bulk density measurements.*

	Density (g ml^{-1}) Untapped	Tapped
Sta-Rx 1500	0·625	0·840
Sta-Rx 1500 + 0·5% magnesium stearate	0·690	0·877
Avicel pH 101	0·309	0·455
Avicel + 0·5% magnesium stearate	0·373	0·463
Lactose 50T	0·758	0·909
Lactose 50T + 0·5% magnesium stearate	0·840	0·917
Lactose 80 mesh	0·500	0·877
Lactose 80 mesh + 0·5% magnesium stearate	0·658	0·926

up of the ejection force. 3C shows the reading after about 20 capsules had been filled, and 3D after about 50 capsules had been filled from the start of the run. Between these figures the ejection force had built up from 45 to 130 N but was reduced to about 2–3 N by the addition of 0·5% w/w magnesium stearate (Fig. 3E).

DISCUSSION

The amount of compression which is given to the powder during plug formation is set by the depth of powder in the filling hopper, and the distance of the end of the dosator piston from the end of the dosator nozzle. These two factors were kept constant and this being so, any differences in value of the forces produced must be due to the nature of the powder being used.

Lactose requires lubrication before tablets can be produced. That this is also true of capsule filling using the plug method can be seen from the rapid ejection force build up in lactose 50T: Fig. 3C in the trace taken after about 20 capsules had been filled and Fig. 3D after about 50. At this stage the noise from the machine was sufficient to indicate that a binding problem existed. The cause is the entrapment of small particles between the inner wall of the dosator nozzle and the flared end of the dosator push rod. That magnesium stearate, 0·5%, overcomes this is seen from Fig. 3E.

Addition of magnesium stearate to lactose 80 mesh resulted in an increase of compaction pressure, a possible explanation for which is that the pressure increase is due to the 5·5% increase in bulk density caused by the glidant effect of the lubricant. Addition of the lubricant to the lactose 50T produced neither a significant increase in

compaction pressure nor in bulk density (0·88%). This is because the coarser and more evenly sized particles of this grade of lactose are more free flowing than those of the lactose 80 mesh, and rapidly assume a maximum packing density in the dosator hopper, whether lubricated or not.

Sta-Rx shows an increase in bulk density of similar magnitude to that of lactose 80 mesh after lubrication (4·4%) but does not show the same increase in compaction pressure. It is possible that the Sta-Rx particles deform more easily under compaction than the lactose particles, and so absorb the energy of compaction more easily.

The effect of 0·5% magnesium stearate on the Avicel was slight. The compression force was not reduced and the carry-over or retention force was only slightly reduced, as was the ejection force. The material would fill satisfactorily without lubrication and this supports the report by Fox, Rickman & others (1963) that Avicel has some lubricant properties. The bulk density of the material did not increase appreciably after lubrication (1·73%).

The retention and ejection forces seen on the Sta-Rx trace (Fig. 3H) were almost eliminated after the addition of 0·5% magnesium stearate (Fig. 3I), as was the negative force which can be seen just after ejection in the trace of the unlubricated material. A force in this direction can only be due to tension in the dosator rod and may be due to the frictional resistance to the return of the dosator rod caused by particles of powder between the rod and the inner surface of the nozzle. This phenomenon was observed consistently with Sta-Rx but not to any great extent with the other materials.

Conclusion

It has been demonstrated that the forces involved during plug formation and ejection during a capsule filling operation can be recorded and measured using strain gauges. The effect of lubrication on the materials has a pronounced effect on the form of the force-time curves, and some aspects of these changes may find a use, for example in the determination of minimum lubricant levels during the formulation of mixes for encapsulation, and optimum mixing time for the powders.

Acknowledgements

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