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TECHNICAL ARTICLES

Simulation Device for Preliminary Tablet Compression Studies

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Abstract □ A system was designed to simulate the double-acting compression effect of rotary tableting machines commonly used to prepare pharmaceutical compressed tablets. The device was constructed for use with a universal mechanical testing instrument, but the principle could also be applied to other types of compressing equipment including a modified reciprocating tablet machine. The double-acting compression is achieved by controlled downward movement of the die at a slower rate than the simultaneous downward movement of the upper punch. Adjustable components also allow control of: (*a*) the rate of loading, (*b*) the relative rate of movement of the die and upper punch, (*c*) the time at which movement of the die commences, (*d*) the depth of compression in the die, and (*e*) precompression of the powder bed. These controls permit simulation of a range of machine settings for different types of rotary tablet presses.

Keyphrases □ Tablet compression—preliminary testing, simulation of double-acting compression cycle of a rotary tableting machine □ Rotary tableting machine—simulation device for preliminary tablet compression testing □ Compression, tablets—preliminary testing, rotary tableting machine simulation device

Since the investigations of Shotton *et al.* (1) and Knoechel *et al.* (2, 3), there has been much interest in the instrumentation of rotary compression machines used for the manufacture of pharmaceutical compressed tablets.

In preformulation studies and during the early stages of development of tablets, the compression behavior of substances is often insufficiently well defined to compress the material on precision equipment such as a rotary machine. Also, sufficient quantities of a new drug substance may not be available at the appropriate time for such large-scale investigations. Preliminary studies, therefore, are often carried out using a single-acting press or a reciprocating tableting machine in which the compression conditions differ from those of a rotary machine with respect to factors such as friction effects at the die wall and stress distribution in a compact. It is often difficult to relate the results of these preliminary trials to the subsequent behavior of the material on a rotary machine.

This report describes a system (4) which is used with a single-acting mechanical press to simulate the double-acting compression cycle of a rotary tableting machine.

OPERATING PRINCIPLE

A diagram of the simulator is shown in Fig. 1. It was designed principally for use with a universal mechanical testing instrument[1] as in Figs. 2 and 3, but many of the design features allow the system to be used in conjunction with other types of mechanical and hydraulic compressing equipment or with a modified reciprocating tablet press.

A rotary tablet machine is double acting; consolidation of the compacted material occurs in a die between upper and lower punches, which move toward each other between compression wheels (Fig. 4). To simulate this effect using a single-acting press in which movement of only one component occurs, such as the upper punch, this movement must be translated also to a second component of the system, such as the lower punch. However, since the principal load-bearing components of such a compression train are the upper and lower punches, it is mechanically simpler to fix the punches to the upper and lower platens of the compressing equipment. For this reason, in the device described the double-acting compression is achieved by controlled downward movement of the die at a rate proportionately less than the downward displacement of the upper punch. The resulting compression effect is the same as if the die were fixed and the lower punch moved upward at a controlled rate equal to, greater than, or less than the downward movement of the upper punch. The system selected also simplifies the measurement of compaction and ejection forces using the Instron machine[1].

DESIGN DETAILS

The schematic diagram of the simulator (Fig. 1) shows the apparatus assembled with 33-mm. diameter plane-faced compression tooling (A, B, and C) from a rotary tablet machine[2]. The upper and

[1] Model TTDM, Instron Corp., Canton, Mass.
[2] Stokes DS3, F. J. Stokes Corp., Philadelphia, Pa.

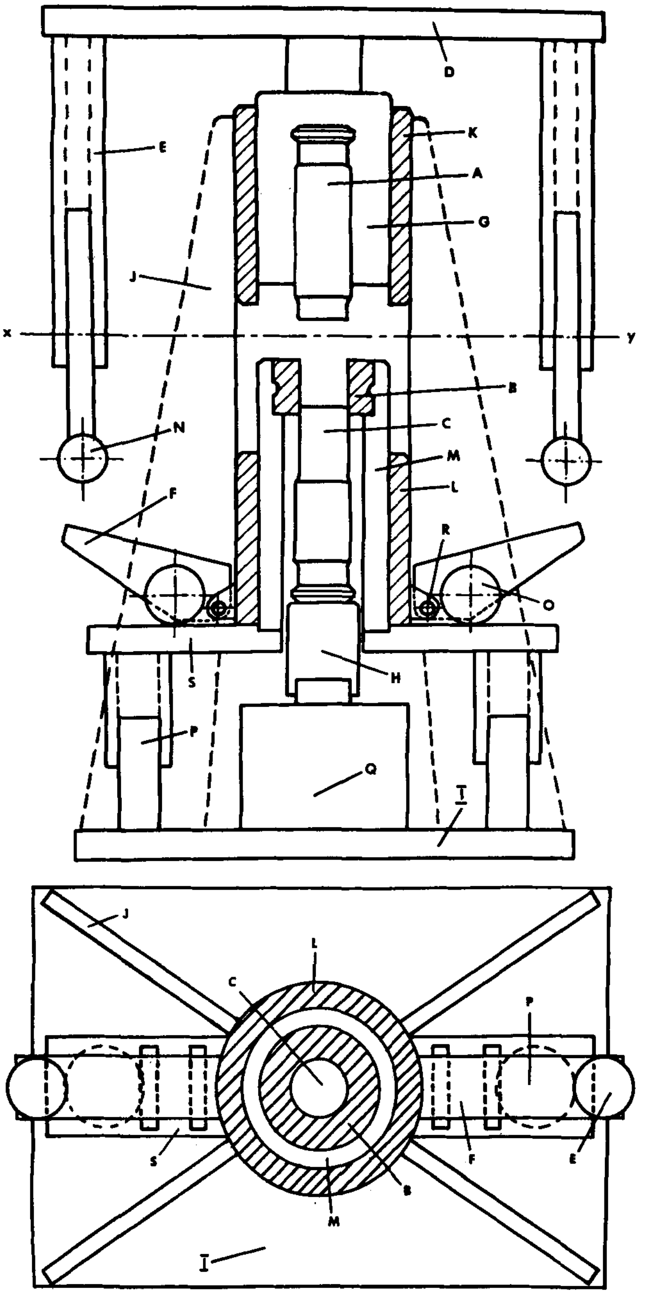

Figure 1—*Schematic diagram of the apparatus to simulate the double-acting compression effect of a rotary tableting machine. Key: upper diagram, vertical section; and lower diagram, plan view of a section through XY.*

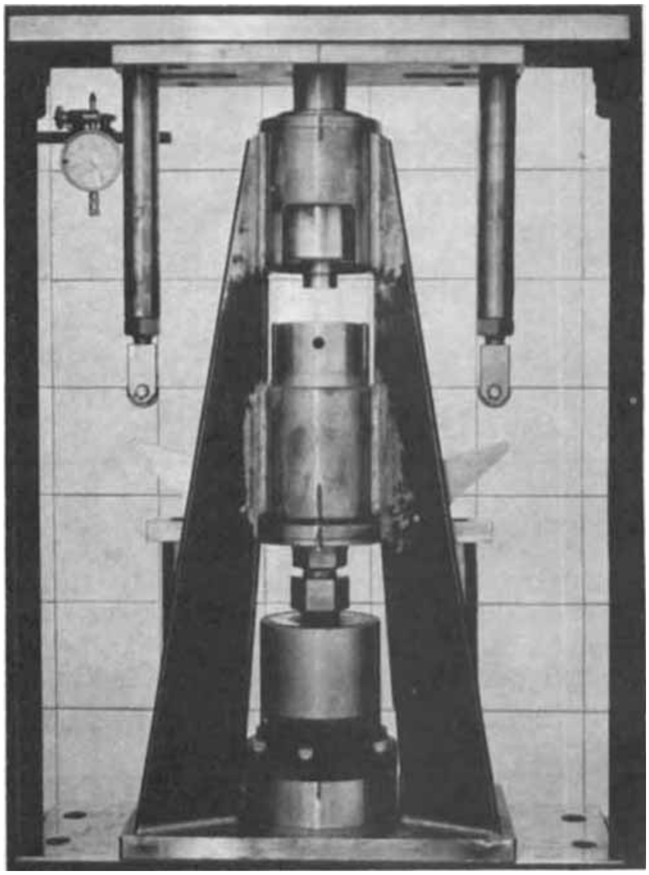

Figure 2—*Photograph of the simulator. The 10-cm. square white tiles in the background indicate the dimensions of the equipment.*

lower punch holders and the die assembly are so constructed that by using appropriate sleeves and distance pieces, alternative tooling from other types of presses can be installed.

The lower punch (C) is located by a sleeve in a guide (M) and supported on a load cell (Q). The guide (M) also acts as a support block for the die. Using the adjustable support cylinder (H), the height of the lower punch can be controlled. The entire lower punch assembly is rigid, being attached to a base plate (I) which is bolted to the stationary lower crosshead of the Instron.

The upper punch is held in a rigid assembly (G) which is fixed to a support plate (D) bolted to the underside of the Instron's movable crosshead.

A cylindrical guide (K) is supported on four pillars (J) which are welded diagonally to the corners of the rectangular base plate (I). This guide cylinder locates the upper punch holder (G) and, therefore, ensures correct alignment of the upper punch with the die. Centration of the die is achieved by a second guide cylinder (L) which is attached to the same four pillars (J). Inserted in the upper surface of this guide cylinder (L) is a sealing gasket which prevents dust from contaminating the contact surface with the die support block (M).

Also fixed to the movable crosshead are two vertical struts (E). The telescopic construction enables their lengths to be altered, and the points of attachment to the support plate (D) on the crosshead are also adjustable in a horizontal track. The die support block (M) rests on a table (S) which is supported by two telescopic pillars (P) containing plate springs.

Powder is introduced manually into the die cavity. As the upper punch (A) moves downward to compress the powder, the lower end of each vertical strut (E) contacts a lever arm (F). Each lever pivots about a fixed axis (R) in an extension of the stationary guide cylinder (L) which is welded to the four rigid support pillars (J). The two levers (F) rest on roller bearings (O) which are in contact with the table (S) carrying the die support block (M). The roller bearings (N and O) reduce friction at the points of contact during movement of the lever arm (F). As the extremity of each lever is depressed by the vertical strut (E), downward displacement of the table (S) causes the die to move downward. The point of contact between the struts (E) and the upper surface of each lever arm (F) can be altered by symmetrical adjustment of the horizontal position of the two struts. This controls the relative rate of movement of the upper punch with respect to the die.

Symmetrical adjustment of the length of both struts (E) controls the time at which downward movement of the die is initiated.

During the compression cycle, the force on the lower punch is measured using the load cell (Q). After compacting the powder to the required pressure, the upper punch is raised using the "rapid return" control of the Instron. A cylindrical distance piece is then placed between the die (B) and the lower surface of the upper punch holder (G). Downward movement of the crosshead supporting the upper punch holder then ejects the compact from the die by forcing the die downward past the lower punch. The ejection force can be monitored using the load cell (Q) which supports the lower punch (C).

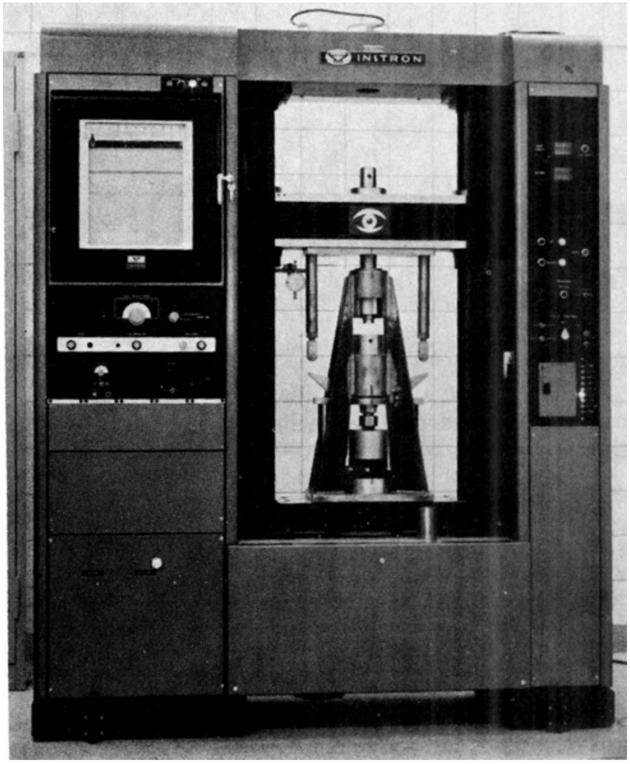

Figure 3—*The simulator installed between the stationary and moveable crossheads of the universal testing instrument. In front of the stationary lower crosshead is the cylindrical distance piece used to depress the die during ejection of tablets.*

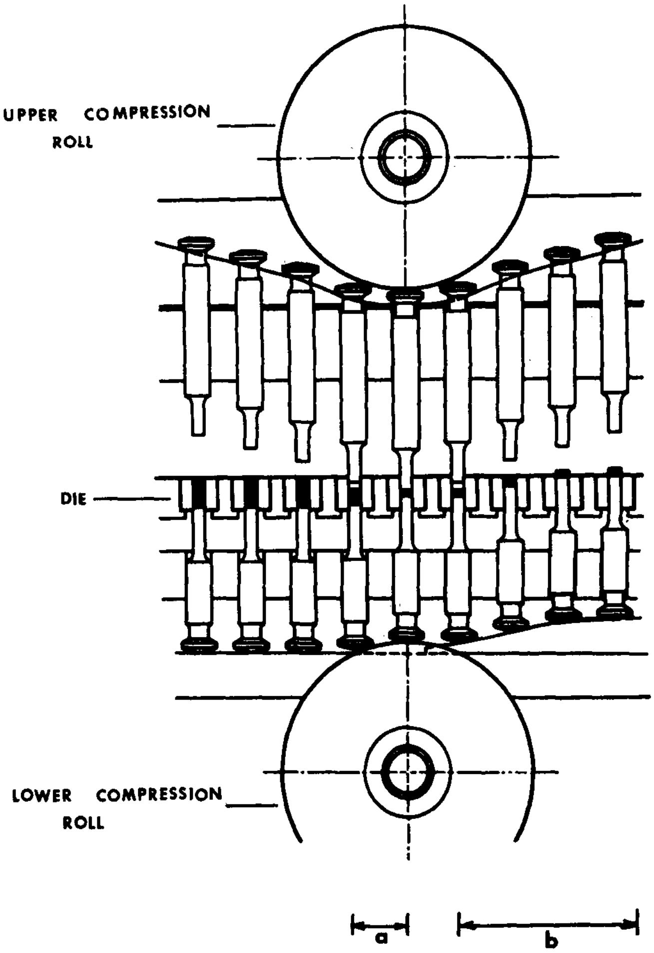

Figure 4—*The compaction cycle of a rotary tableting machine. Key: a, compression; and b, ejection.*

POTENTIAL APPLICATIONS

The simulator is primarily of use in preformulation studies to characterize the compression properties of single substances and in preliminary formulation experiments, for example, to assess the required quantities of excipients such as lubricants. For these purposes, instrumentation of the apparatus to monitor compression forces, ejection force, and punch displacement is much less complex than with a rotary tableting machine.

An alternative application of the device is the preparation of small quantities of tablets for which special precautions are necessary. For example, when compressing tablets containing radioactive marked substances for tracer studies, large-scale equipment such as a rotary tableting machine is often unsuitable.

Differences between various types of rotary machines may be caused by the interaction of factors such as the rate of die–table rotation, the spacing of dies in the table, the size and relative position of the upper and lower compression wheels, the shape of punch cam-tracks, the depth at which tablets are compressed in the die, and precompression facilities. To evaluate the effect of these parameters using the simulation device, several factors must be variable, namely, the rate of compression, the relative rate of punch and die movement, the time of onset of die movement, and the maximum applied load.

Although when used with the universal testing instrument the maximum loading rates are lower than those of conventional rotary tablet machines, the use of the simulation system with other types of compressing equipment such as a modified reciprocating tablet press permits compression at higher rates. The precise control of loading rate that is possible with a universal testing instrument does, however, allow investigation of the effect of different loading rates on tablet properties.

During compression on a rotary machine, the strain in the powder bed is increasing continually with applied force, but the *rate* of strain is not constant. The strain rate is highest when the punch first contacts the pressure wheel; as the punch approaches the point of maximum compression, the rate of strain decreases to zero. To simulate this effect with a hydraulic or mechanical press, the rate of movement could be programmed according to the particular rotary machine setting to be simulated. In practice, as shown in Fig. 4, the arc through which the punch moves in a rotary machine is only a fraction of the pressure wheel's total circumference. Especially with a large pressure wheel, this arc is almost linear. The approximation involved in utilizing a constant rate of strain is small.

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